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Limon

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(54) **DRUG ELUTING STENT**

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A61F 2/06 (2006.01)

(52) **U.S. Cl.** **623/1.15**; 623/1.39; 623/1.42

(58) **Field of Classification Search** 623/1.15, 623/1.43, 1.42, 1.46, 1.39
See application file for complete search history.

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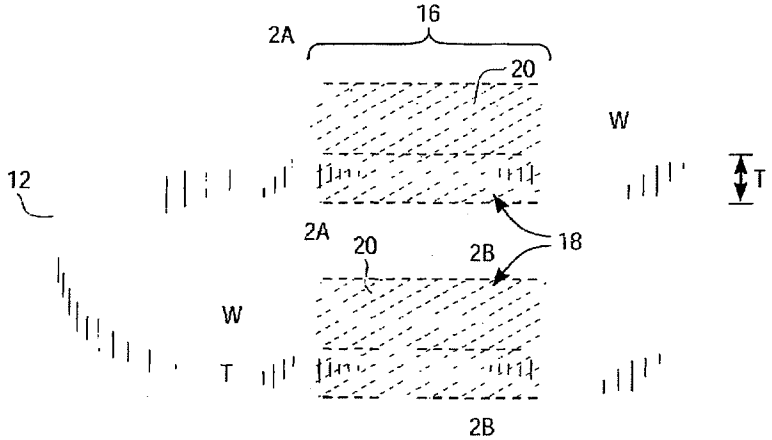
(57) **ABSTRACT**

Stents having struts with narrowed portions are described. The narrowed portions have a coating disposed thereon for the local delivery of a drug.

62 Claims, 3 Drawing Sheets



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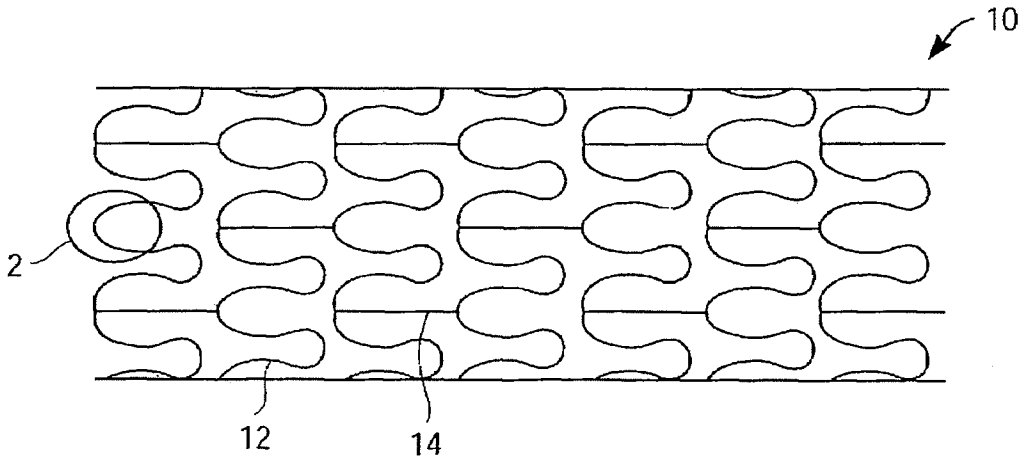

FIG. 1

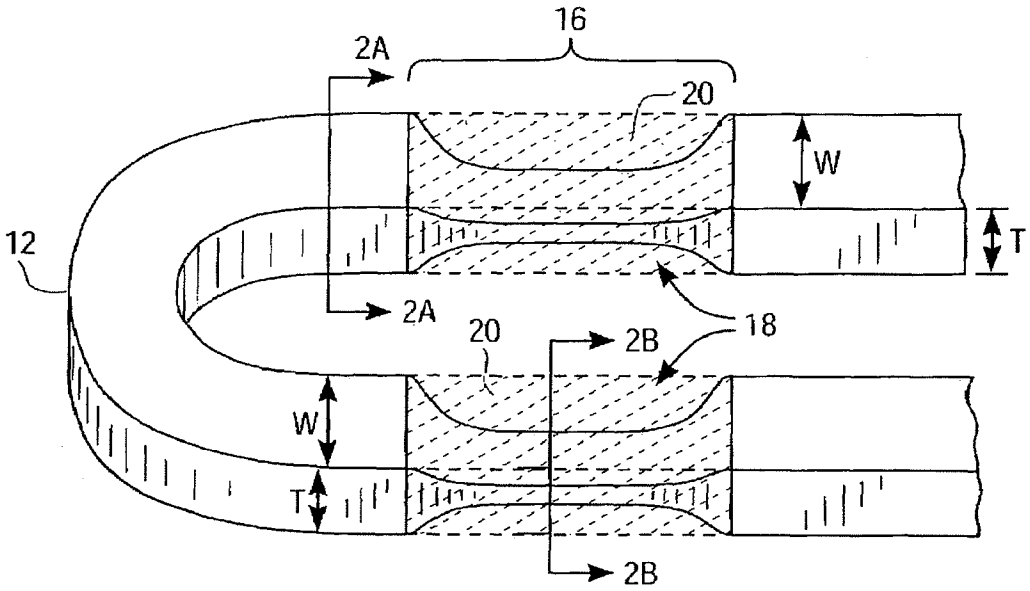

FIG. 2

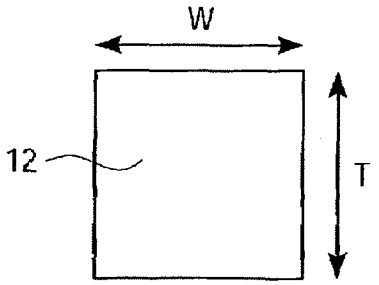

FIG. 2A

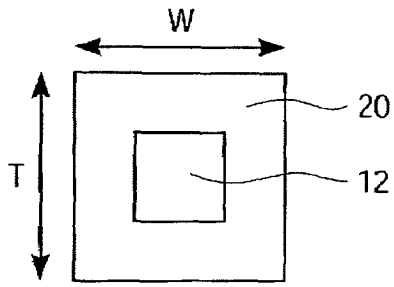

FIG. 2B

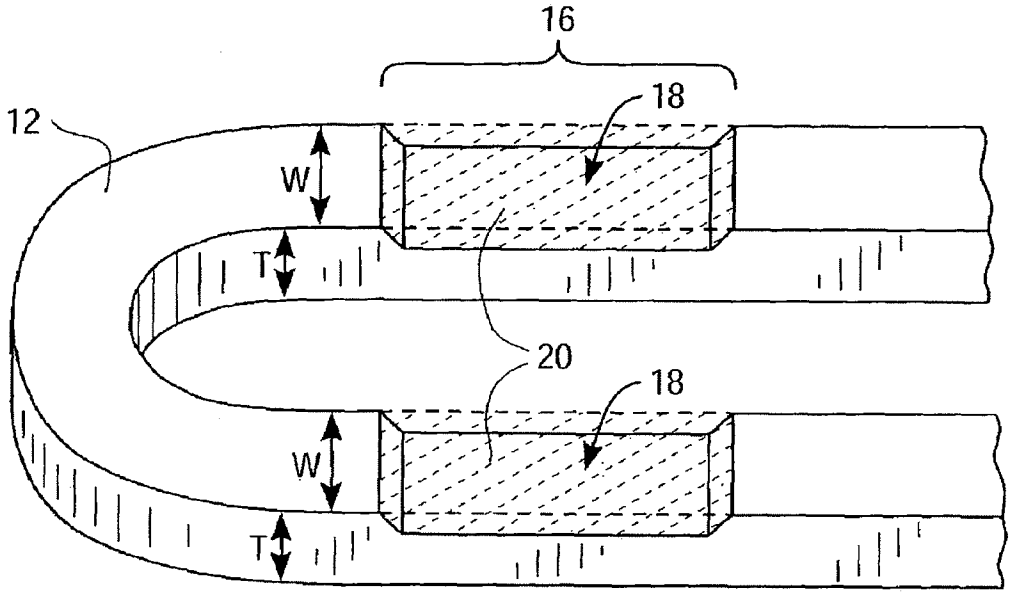

FIG. 3

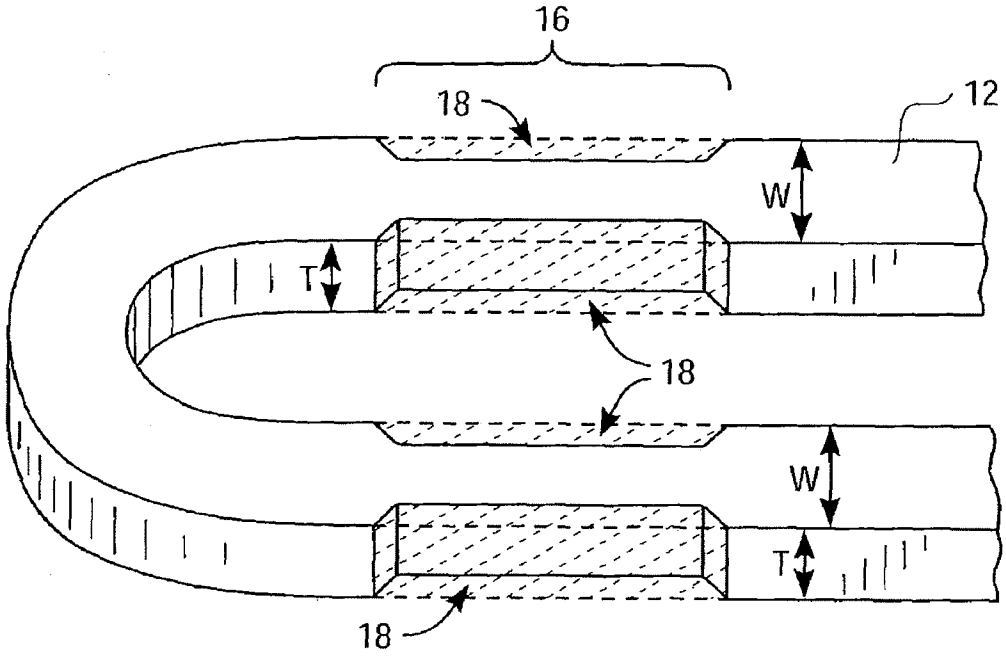

FIG. 4

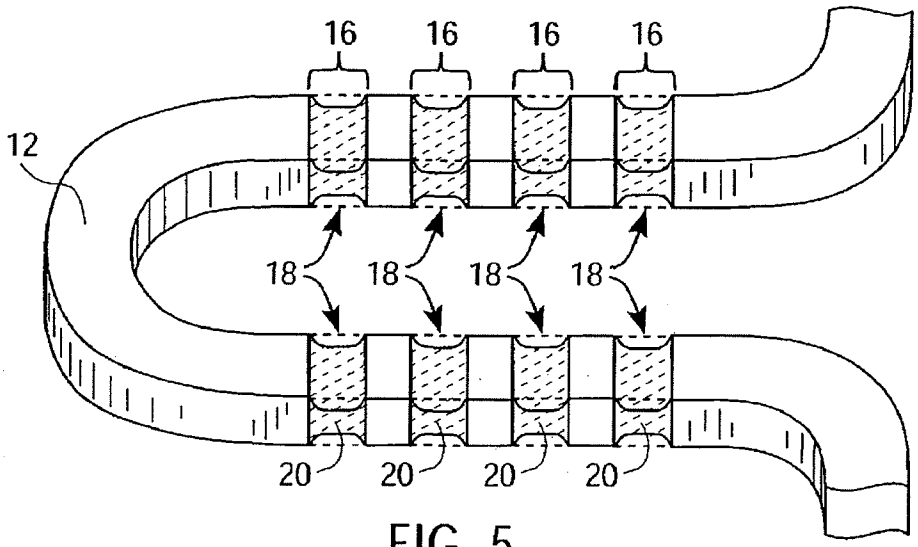

FIG. 5

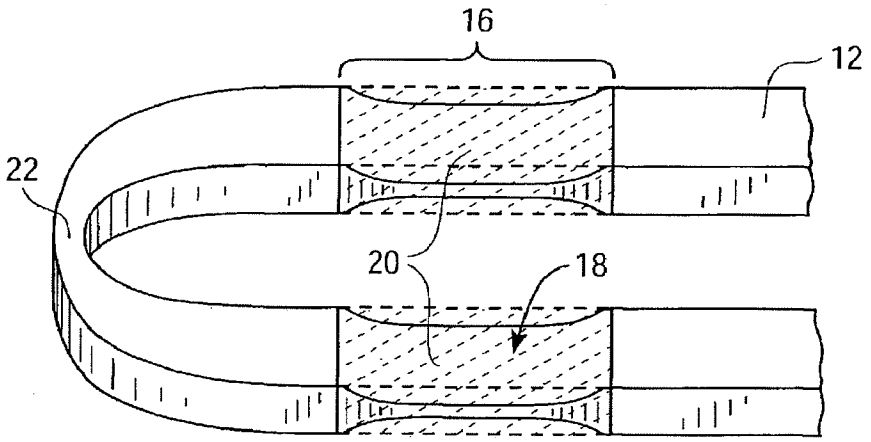

FIG. 6A

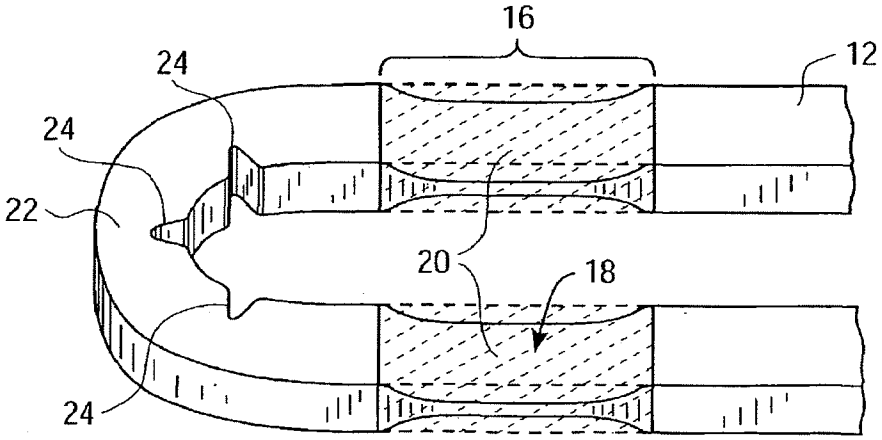

FIG. 6B

DRUG ELUTING STENT

BACKGROUND

This invention relates to implantable medical devices, such as stents. More particularly, this invention relates to a stent having drug delivery capabilities.

Percutaneous transluminal coronary angioplasty (PTCA) is a procedure for treating heart disease. A catheter assembly having a balloon portion is introduced into the cardiovascular system of a patient via the brachial or femoral artery. The catheter assembly is advanced through the coronary vasculature until the balloon portion is positioned across the occlusive lesion. Once in position across the lesion, the balloon is inflated to a predetermined size to radially compress against the atherosclerotic plaque of the lesion to remodel the lumen wall. The balloon is then deflated to a smaller profile to allow the catheter to be withdrawn from the patient's vasculature.

A problem associated with the procedure includes formation of intimal flaps or torn arterial linings that can collapse and occlude the conduit after the balloon is deflated. Moreover, thrombosis and restenosis of the artery can develop over several months after the procedure, which can require another angioplasty procedure or a surgical bypass operation. To reduce the partial or total occlusion of the artery by the collapse of arterial lining and to reduce the chance of the development of thrombosis and restenosis, an intraluminal prosthesis, an example of which includes an expandable stent, is implanted in the lumen to maintain the vascular patency. Stents are scaffolding structures, usually cylindrical or tubular in shape, functioning to physically hold open, and if desired, to expand the wall of the passageway. Typically stents are capable of being compressed for insertion through small cavities via small catheters, and then expanded to a larger diameter once at the desired location.

To treat the damaged vasculature tissue and further fight against thrombosis and restenosis, there is a need to administer therapeutic substances to the treatment site. For example, anticoagulants, antiplatelets and cytostatic agents are commonly used to prevent thrombosis of the coronary lumen, to inhibit development of restenosis, and to reduce post-angioplasty proliferation of the vascular tissue. To provide an efficacious concentration to the treated site, systemic administration of medication can produce adverse or toxic side effects for the patient. Local delivery is a highly suitable method of treatment in that smaller levels of medication, as compared to systemic dosages, are concentrated at a specific site. Local delivery produces fewer side effects and achieves more effective results.

One commonly applied technique for the local delivery of the drugs is through the use of medicated stents. One method of medicating stents involves the use of a polymeric carrier coated onto the body of the stent. A polymer dissolved in a solvent and a drug added thereto can be applied to the stent. Once the solvent evaporates, a coating of the polymer containing the drug remains on the stent. The embodiments of the present invention provide various stent structures for containing a coating, such as a polymeric coating, for the local delivery of a drug.

SUMMARY

In accordance with one embodiment, a stent is disclosed comprising a strut having a first segment, a second segment and a third segment located between the first and second segments, wherein the transverse cross sectional area of the third segment is less than the transverse cross sectional area of the first segment and the second segment; and a coating disposed on the third segment of the strut, wherein the first and second segments of the strut are free of any coating. In one embodiment, the coating is disposed all the way around the third segment of the strut. The outer surface of the coating should not extend beyond the outer surface of the first or second segment of the strut. The coating can be made from a polymeric material containing a therapeutic substance. In accordance with one embodiment, the strut includes a linear segment extending into a curved segment, wherein the first, second and third segments define a part of the linear segment of the strut. The curved segment can include a notch or can be smaller in thickness or width than the first or second segment of the strut.

In accordance with another embodiment of the invention, a radially expandable stent is provided comprising a strut, at least a segment of the strut having a circumference smaller than the circumference of a remaining portion of the strut; and a coating supported by the segment of the strut having the smaller circumference. The strut can include four sides, wherein the width of the segment of the strut having the smaller circumference is less than the width of the remaining portion of the strut. Alternatively, the thickness of the segment of the strut having the smaller circumference is less than the thickness of the remaining portion of the strut. The coating can, for example, surround the segment of the strut having the reduced circumference. The remaining portion of the strut having the larger circumference can be free from any coating.

In accordance with another embodiment of the invention, a method of manufacturing a drug eluting stent is provided, comprising depositing a coating on a first segment of a strut of the stent, the stent including a second segment and a third segment, wherein the first segment is positioned between the second segment and the third segment, the first segment having a smaller transverse cross sectional area than the transverse cross sectional area of the second or third segment.

In accordance with another embodiment of the invention, a method of manufacturing a drug eluting stent is provided, comprising depositing a coating on a stent, the stent including a strut having a first segment, a second segment, and a third segment located between the first and second segments, wherein the transverse cross sectional area of the third segment is less than the transverse cross sectional area of the first segment and the second segment; and removing the coating off of the first and second segments so that the coating remains on the third segment.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates an embodiment of a conventional stent;

FIG. **2** is an enlarged perspective view of the stent strut of encircled region **2** of FIG. **1**;

FIGS. **2**A and **2**B are transverse cross sectional views along the line **2**A—**2**A and **2**B—**2**B, respectively, of FIG. **2**; and

FIGS. **3**, **4**, **5**, **6**A, and **6**B are perspective views of a stent strut according to other embodiments of the invention.

DETAILED DESCRIPTION

FIG. **1** illustrates one embodiment of a stent **10** that can be used with the practice of the present invention. Stent **10** can be generally cylindrical and radially self- or balloon-expandable. Stent **10** can be inserted and deployed in a

patient with an appropriate delivery device such as a balloon dilatation catheter. Stent **10** can be made, for example, from a plurality of wave-like or serpentine-like struts **12** having curved segments and generally linear segments. Struts **12** are connected to the adjacent struts **12** via connecting elements **14**. The embodiments of the present invention, however, should not be limited to the structure of FIG. **1**. A variety of other scaffolding designs can also be used, such as "V" shaped struts or struts having a "zigzag" formation.

Referring to FIG. **2**, the linear section of strut **12** includes a segment, referred to by reference number **16**, wherein any transverse cross sectional portion of segment **16** has a smaller cross sectional surface area than the remaining segment of strut **12**. FIG. **2A** illustrates a transverse cross sectional view of strut **12** of FIG. **2** taken along the line **2A**—**2A**. FIG. **2B** illustrates a transverse cross sectional view of strut **12** of FIG. **2** taken along the line **2B**—**2B**. As illustrated by FIGS. **2A** and **2B**, segment **16** has a reduced thickness and width, which provides for a smaller circumference, as compared to the remaining portions of strut **12**.

FIGS. **2**, **2A** and **2B** illustrate a four-sided strut **12** wherein segment **16** has a reduced width W as well as thickness T. Struts **12** need not be four-sided, however, and can have any suitable transverse cross sectional geometry, such as a three sided, oval or circular struts. The reduced circumferential size of segment **16** defines a recessed volume **18** in which a coating **20** can be deposited. Coating **20** can be a drug or a therapeutic composition or can contain the drug. Coating **20** can be made from any suitable biocompatible polymer, examples of which are disclosed below. As best illustrated by FIG. **2**, the remaining segments of strut **12** can be free from any substances or coatings. Coating **20** can be disposed all the way around segment **16** as coating **20** can completely encapsulate the narrowed segment **16** of strut **12**. Recessed volume **18** can be fully filled with the coating substance such that the outer surfaces of coating **20** are "flush" with their respective outer surfaces of strut **12**. In other words, the outer dimensions of coating **20** can equal the outer dimensions of strut **12**, thereby creating a smooth transition between the surfaces of coating **20** and the surfaces of strut **12**, thus minimizing intravascular flow turbulence around stent **10**.

In accordance with another embodiment of the invention, as illustrated in FIG. **3**, strut **12** can have a variable thickness T, but a constant width W. As best illustrated by FIG. **3**, width W of strut **12** is the same, but thickness T is reduced along segment **16** of strut **12**. The reduced thickness T provides recessed volume **18** containing coating **20** on the outer surface or tissue-contacting surface of strut **12**. Although not illustrated, a recessed volume **18** can also be provided in the inner or lumen surface of strut **12**.

In accordance with another embodiment, as illustrated by FIG. **4**, a variable width W for strut **12** can be provided, while maintaining the thickness T constant. As best illustrated by FIG. **4**, thickness T of strut is the same, but width W is reduced along segment **16** of strut **12**. FIG. **4** illustrates recessed volumes **18** on opposing sides of strut **12**. However, as is the case with FIG. **3**, recessed volume **18** can be about only one of the two sides of strut **12**.

Transition zones leading into segment **16** can be gradual, with a slight slop, as illustrated by FIG. **2** or can be a relatively sharp drop-off, as illustrated by FIG. **3** or **4**. The smallest transverse cross sectional area in segment **16** can be up to about 50% smaller than the transverse cross sectional area of the remaining portions of strut **12**. One having ordinary skill in the art should be cautious of mechanical fatigue and failure that could be caused if the circumference of segment **16** is too small or if the transition zone is sloped too non-compliant. Exemplary dimensions and design of strut **12** depend, of course, on an variety of factors including the material from which strut **12** is made, the length of segment **16**, and the application for which stent **10** will be used. Accordingly, there is a tradeoff between trying to maximize recess volume **18** for maximizing drug delivery capabilities and eliminating mechanical failure that can be caused by radial expansion and use of stent **10**.

In accordance with yet another embodiment, as illustrated in FIG. **5**, any number of suitable segments **16** having a reduced circumferential area can be included in strut **12**. Having a multitude of segments **16** allows for the incorporation of more than one type of therapeutic substance in different areas of stent **10**. Accordingly, a variety of cocktail combinations of drugs can be delivered via stent **10**. The longitudinal span of each segment **16** depends on the number of segments **16** that are to be incorporated into strut **12** and the length of strut **12**, among other factors.

In accordance with yet another embodiment of the invention, FIG. **6A** illustrates strut **12** having a thinned section, in either thickness or width, in the curved portion (as designated by reference number **22**) of strut **12**. Alternatively, as illustrated in FIG. **6B** notches **24** can be provided in curved portion **22** of strut **12**. The thinned section and/or pivot notches **24** in curved portion **22** of strut **12** can produce a weakened bending region for stent **10**. The weakened bending region can maximize bending along curved region **22** or at pivot notches **24** and minimize stress along the linear portion of strut **12**. This is advantageous in preserving the structural integrity of coating **20** so as to prevent or reduce fragmentation of coating during the radial expansion of stent **10**.

Struts **12** can be made from a metallic material or an alloy such as, but not limited to, cobalt chromium alloy (ELGILOY), stainless steel (316L), "MP35N," "MP20N," ELASTINITE (nitinol), tantalum, nickel-titanium alloy, platinum-iridium alloy, gold, magnesium, or combinations thereof. "MP35N" and "MP20N" are trade names for alloys of cobalt, nickel, chromium and molybdenum available from Standard Press Steel Co., Jenkintown, Pa. "MP35N" consists of 35% cobalt, 35% nickel, 20% chromium, and 10% molybdenum. "MP20N" consists of 50% cobalt, 20% nickel, 20% chromium, and 10% molybdenum. Struts **12** can also be made from bioabsorbable or biostable polymers.

The drug, therapeutic substance or active agent, terms which are used interchangeably, in the coating **20** can inhibit the activity of vascular smooth muscle cells. More specifically, the active agent can be aimed at inhibiting abnormal or inappropriate migration and/or proliferation of smooth muscle cells for the inhibition of restenosis. The active agent can also include any substance capable of exerting a therapeutic or prophylactic effect for a diseased condition. For example, the agent can be for enhancing wound healing in a vascular site or improving the structural and elastic properties of the vascular site. Examples of agents include antiproliferative substances such as actinomycin D, or derivatives and analogs thereof (manufactured by Sigma-Aldrich, Inc., Milwaukee, Wis.; or COSMEGEN available from Merck & Co., Inc., Whitehorse Station, N.J.). Synonyms of actinomycin D include dactinomycin, actinomycin IV, actinomycin I_1, actinomycin X_1, and actinomycin C_1. The active agent can also fall under the genus of antineoplastic, anti-inflammatory, antiplatelet, anticoagulant, antifibrin, antithrombin, antimitotic, antibiotic, antiallergic and antioxidant substances. Examples of such antineoplastics and/or antimitotics include paclitaxel (e.g., TAXOL® by

Bristol-Myers Squibb Co., Stamford, Conn.), docetaxel (e.g., Taxotere®, from Aventis S. A., Frankfurt, Germany), methotrexate, azathioprine, vincristine, vinblastine, fluorouracil, doxorubicin hydrochloride (e.g., Adriamycin® from Pharmacia & Upjohn, Peapack, N.J.), and mitomycin (e.g., Mutamycin® from Bristol-Myers Squibb Co.). Examples of such antiplatelets, anticoagulants, antifibrin, and antithrombins include sodium heparin, low molecular weight heparins, heparinoids, hirudin, argatroban, forskolin, vapiprost, prostacyclin and prostacyclin analogues, dextran, D-phe-pro-arg-chloromethylketone (synthetic antithrombin), dipyridamole, glycoprotein IIb/IIIa platelet membrane receptor antagonist antibody, recombinant hirudin, and thrombin inhibitors such as Angiomax ä (Biogen, Inc., Cambridge, Mass.). Examples of such cytostatic or antiproliferative agents include angiopeptin, angiotensin converting enzyme inhibitors such as captopril (e.g., Capoten® and Capozide® from Bristol-Myers Squibb Co.), cilazapril or lisinopril (e.g., Prinivil® and Prinzide® from Merck & Co., Inc.), calcium channel blockers (such as nifedipine), colchicine, fibroblast growth factor (FGF) antagonists, fish oil (omega 3-fatty acid), histamine antagonists, lovastatin (an inhibitor of HMG-CoA reductase, a cholesterol lowering drug, brand name Mevacor® from Merck & Co., Inc.), monoclonal antibodies (such as those specific for Platelet-Derived Growth Factor (PDGF) receptors), nitroprusside, phosphodiesterase inhibitors, prostaglandin inhibitors, suramin, serotonin blockers, steroids, thioprotease inhibitors, triazolopyrimidine (a PDGF antagonist), and nitric oxide. An example of an antiallergic agent is permirolast potassium. Other therapeutic substances or agents which may be appropriate include alpha-interferon, genetically engineered epithelial cells, rapamycin and its derivatives and analogs, and dexamethasone.

Coating **20** can be made from any suitable biocompatible polymer, examples of which include ethylene vinyl alcohol copolymer (commonly known by the generic name EVOH or by the trade name EVAL); poly(hydroxyvalerate); poly (L-lactic acid); polycaprolactone; poly(lactide-co-glycolide); poly(hydroxybutyrate); poly(hydroxybutyrate-co-valerate); polydioxanone; polyorthoester; polyanhydride; poly(glycolic acid); poly(D,L-lactic acid); poly(glycolic acid-co-trimethylene carbonate); polyphosphoester; polyphosphoester urethane; poly(amino acids); cyanoacrylates; poly(trimethylene carbonate); poly(iminocarbonate); copoly (ether-esters) (e.g., PEO/PLA); polyalkylene oxalates; polyphosphazenes; biomolecules, such as fibrin, fibrinogen, cellulose, starch, collagen and hyaluronic acid; polyurethanes; silicones; polyesters; polyolefins; polyisobutylene and ethylene-alphaolefin copolymers; acrylic polymers and copolymers; vinyl halide polymers and copolymers, such as polyvinyl chloride; polyvinyl ethers, such as polyvinyl methyl ether; polyvinylidene halides, such as polyvinylidene fluoride and polyvinylidene chloride; polyacrylonitrile; polyvinyl ketones; polyvinyl aromatics, such as polystyrene; polyvinyl esters, such as polyvinyl acetate; copolymers of vinyl monomers with each other and olefins, such as ethylene-methyl methacrylate copolymers, acrylonitrile-styrene copolymers, ABS resins, and ethylene-vinyl acetate copolymers; polyamides, such as Nylon 66 and polycaprolactam; alkyd resins; polycarbonates; polyoxymethylenes; polyimides; polyethers; epoxy resins; polyurethanes; rayon; rayon-triacetate; cellulose; cellulose acetate; cellulose butyrate; cellulose acetate butyrate; cellophane; cellulose nitrate; cellulose propionate; cellulose ethers; and carboxymethyl cellulose. Coating **20** can also be silicon foam, neoprene, santoprene, or closed cell foam.

Stent **10** can be constructed, for example, from a tube of a desired strut material. The tube can be mounted onto a mandrel and angular grooves can be cut into the outer surface of the tube by a lathe or a Swiss screw, for example KJR-16 Swiss Screw Machine available from STAR CNC Automatic Lathe in Shizuoka, Japan. The shape of strut **12** can then be radially cut from the tube by a laser. The laser cutting can also produce the thinned curved section **22** or pivot notches **24** illustrated in FIGS. **6**A and **6**B. Struts **12** can be electropolished to reshape or round off sharp corners.

Stent **10** can then be mounted on a Teflon® or paralyne coated mandrel fixed to a two-dimensional actuator controlled by a computer numerical control (CNC) controller, for example a Model DR500 available from Aerotek, Inc., Pittsburgh, Pa. The two-dimensional actuator can translate and rotate stent **10** about the longitudinal axis of stent **10**. A fluid applicator device, for example a Model 1500XL available from EFD, Inc., East Providence, R.I., with a needle tip, can be fixed adjacent to the mounted stent **10** and ejection of a coating substance can be controlled by the CNC controller. The needle tip can have an outer diameter of about 0.02 mm (0.0008 in.) to about 0.038 mm (0.0015 in.) and an inner diameter from about 0.005 mm (0.0002 in.) to about 0.02 mm (0.0009 in.). The CNC controller then causes ejection of coating **20** in a liquid state from the needle tip into recessed volume **18** and simultaneously moves stent **10** longitudinally to spread coating **20** evenly in recessed volume **18**. Once recessed volume **18** of segment **16** is coated with a desired volume of coating **20**, ejection of the coating substance ceases and stent **10** can be moved until the next uncoated recessed volume **18** is adjacent to the needle tip of the fluid applicator device. The process can repeat until all the recessed volumes **18** are coated. The needle tip should also be capable of being raised and lowered relative to stent **10** by the CNC controller particularly when coating small volumes necessitates direct contact between the needle tip and stent **10**.

Alternatively, coating **20** can be deposited in recessed volumes **18** by crimping stent **10** onto a mandrel covered with a soft material (for examples, having a D hardness rating of about 20 to about 50, such as silicon foam, neoprene, santoprene, or a closed cell foam). In a relaxed state, the soft material can have, for example, a soft material thickness of at least the thickness of strut **12**. The mandrel and stent **10** can then be dipped into the coating substance or the coating substance can be sprayed onto stent **10**. The mandrel and stent **10** can then be pulled through an orifice with a clearance around strut **12** of less than about 0.003 mm (0.0001 in.), more narrowly less than about 0.001 mm (0.00005 in.). Stent **10** can also be pulled over a reamer to scrape off excess coating substance.

In accordance with another embodiment of the invention, masking techniques as is known to a person having ordinary skill in the art can be used to deposit coating **20** in recessed volumes **18** of segment **16**.

While particular embodiments of the present invention have been shown and described, it will be obvious to those having ordinary skill in the art that changes and modifications can be made without departing from this invention. Therefore, the appended claims are to encompass within their scope all such changes and modifications as they fall within the true spirit and scope of the invention.

What is claimed is:

1. A stent, comprising:

a strut having a first unitary segment, a second unitary segment and a third unitary segment along a length of the strut, the third unitary segment being located

between the first and second unitary segments, wherein a circumference around the third unitary segment is less than a circumference around the first unitary segment and the circumference around the third unitary segment is less than a circumference around the second unitary segment, such that a recessed volume of the strut is provided at the third unitary segment, the recessed volume being all the way around the circumference of the third unitary segment; and

a coating disposed all the way around the circumference of the third unitary segment including the recessed volume of the strut, wherein the first and second unitary segments of the strut are free of any coating.

2. The stent of claim **1**, wherein the strut has a rectangular, triangular, oval or circular cross-sectional shape.

3. The stent of claim **1**, wherein the coating is made from a polymeric material containing a therapeutic substance.

4. The stent of claim **1**, wherein the strut includes a linear unitary segment extending into a curved or bent unitary segment, and wherein the first, second and third unitary segments define a part of the linear unitary segment of the strut.

5. The stent of claim **1**, wherein an outer surface of the coating does not extend beyond an outer surface of the first and second unitary segments of the strut.

6. A stent, comprising:

a strut having a first segment, a second segment and a third segment located between the first and second segments, wherein the transverse cross-sectional area of the third segment is less than the transverse cross-sectional area of the first segment and the second segment such that a recessed volume of the strut is provided all the way around a circumference of the third segment, and wherein the strut includes a linear segment extending into a curved or bent segment, the first, second and third segments defining a part of the linear segment of the strut, wherein the curved or bent segment includes a notch carved out from the surface of the strut; and

a coating disposed on the third segment of the strut, wherein the first and second segments of the strut are free of any coating.

7. The stent of claim **6**, wherein the strut has a rectangular, triangular, oval or circular cross-sectional shape.

8. The stent of claim **6**, wherein an outer surface of the coating does not extend beyond an outer surface of the first and second segments of the strut.

9. The stent of claim **6**, wherein the coating includes a drug.

10. A stent, comprising:

a strut having a first unitary segment, a second unitary segment and a third unitary segment located between the first and second unitary segments, wherein the transverse cross-sectional area of the third unitary segment is less than the transverse cross-sectional area of the first unitary segment and the second unitary segment such that a recessed volume of the strut is provided all the way around a circumference of the third unitary segment, and wherein the strut includes a linear unitary segment extending into a curved or bent unitary segment, the first, second and third unitary segments defining a part of the linear unitary segment of the strut, wherein at least a unitary segment of the curved or bent unitary segment is smaller in thickness or width than the first or second unitary segment of the strut; and

a coating disposed on the third unitary segment of the strut, wherein the first and second unitary segments of the strut are free of any coating.

11. The stent of claim **10**, wherein the strut has a rectangular, triangular, oval or circular cross-sectional shape.

12. The stent of claim **10**, wherein the coating includes a drug.

13. A radially expandable stent, comprising:

a unitary strut segment having four sides including two pairs of opposing sides, each of the opposing sides having an outer surface, wherein the outer surfaces of each pair of opposing sides face in different directions, wherein each of the outer surfaces of one pair of opposing sides has a unitary segment defined by a recessed volume completely filled with a coating substance.

14. The stent of claim **13**, wherein a width of each of the outer surfaces of the other pair of opposing sides is smaller in the unitary segment including the recessed volume than a width of a remaining portion of the strut unitary segment.

15. The stent of claim **13**, wherein a thickness of each of the outer surfaces of the other pair of opposing sides is smaller in the unitary segment including the recessed volume than a thickness of a remaining portion of the unitary strut segment.

16. The stent of claim **13**, wherein the coating substance includes a polymeric material.

17. The stent of claim **13**, wherein a remaining portion of the unitary strut segment is free from any coating.

18. The stent of claim **13**, wherein the coating substance includes a therapeutic substance for the treatment of restenosis.

19. The stent of claim **13**, wherein each of the outer surfaces of the other pair of opposing sides is free from the coating substance.

20. A method of manufacturing a stent, comprising:

depositing a coating on a first segment of a strut of the stent, the stent including a second segment and a third segment along the length of the strut, the first segment being positioned between the second segment and the third segment, wherein a circumference around the first segment is less than a circumference around the second segment and the circumference around the first segment is less than a circumference around the third segment, such that a recessed volume of the strut is provided at the first segment, the recessed volume being all the way around the circumference of the first segment, wherein the coating is disposed all the way around the circumference of the first segment including the recessed volume of the strut; and

removing the coating off of the second and third segments so that the coating remains on the first segment.

21. The method of claim **20**, wherein the strut has a rectangular, triangular, oval or circular cross-sectional shape.

22. The method of claim **20**, wherein an outer surface of the coating does not extend beyond an outer surface of the second and third segments of the strut.

23. The method of claim **20**, wherein the coating includes a drug.

24. A method of manufacturing a stent, comprising:

depositing a coating on a stent, the stent including a strut having a first segment, a second segment and a third segment along the length of the strut, the third segment located between the first and second segments, wherein the width of the third segment is less than the width of the first segment and of the second segment, and the

thickness of the third segment is less than the thickness of the first segment and of the second segment, wherein the width and the thickness of the third segment are such that a recessed volume of the strut is provided at the third segment, the recessed volume being all the way around the circumference of the third segment; and

removing the coating off of the first and second segments so that the coating remains on the third segment.

25. The method of claim **24**, wherein an outer surface of the coating does not extend beyond an outer surface of the first and second segments of the strut.

26. The method of claim **24**, wherein the coating includes a drug.

27. A stent, comprising:

a strut having a first unitary segment, a second unitary segment and a third unitary segment along the length of the strut, the third unitary segment being located between the first and second unitary segments, wherein the width of the third unitary segment is less than the width of the first unitary segment and of the second unitary segment, and the thickness of the third unitary segment is less than the thickness of the first unitary segment and of the second unitary segment, wherein the strut portion of the third unitary segment is free of recesses such that the recessed volume is not a recess; and

a coating disposed on the third segment of the strut, wherein the first and second unitary segments of the strut are free of any coating.

28. The stent of claim **27**, wherein the coating is made from a polymeric material containing a therapeutic substance.

29. The stent of claim **27**, wherein the strut includes a linear unitary segment extending into a curved or bent unitary segment, and wherein the first, second and third unitary segments define a part of the linear unitary segment of the strut.

30. The stent of claim **29**, wherein the curved or bent unitary segment is smaller in thickness or width than the first or second unitary segment of the strut.

31. A stent comprising:

a strut having a first segment, a second segment and a third segment along the length of the strut, the third segment being located between the first and second segments, wherein the width of the third segment is less than the width of the first segment and of the second segment, and the thickness of the third segment is less than the thickness of the first segment and of the second segment, wherein the strut portion of the third segment is free of recesses such that the recessed volume is not a recess; and

a coating disposed on the third segment of the strut, wherein the first and second segments of the strut are free of any coating,

wherein an outer surface of the coating is fully filled and flush with an outer surface of the first or second segment of the strut.

32. A stent, comprising a strut having a first segment, a second segment and a third segment along the length of the strut, the third segment being located between the first and second segments, wherein the width of the third segment is less than the width of the first segment and of the second segment, and the thickness of the third segment is less than the thickness of the first segment and of the second segment, wherein the strut portion of the third segment is free of recesses; and

a coating disposed on the third segment of the strut, wherein the first and second segments of the strut are free of any coating,

wherein the strut includes a linear segment extending into a curved or bent segment, and wherein the first, second and third segments define a part of the linear segment of the strut,

wherein the curved or bent segment includes a notch carved out from the surface of the strut.

33. A stent, comprising a strut having a unitary segment defined by a recessed volume disposed all the way around a circumference of the strut, wherein a coating at least partially fills the recessed volume.

34. The stent of claim **33**, wherein an outer surface of the coating does not extend beyond an outer surface of a nonrecessed portion of the strut.

35. The stent of claim **33**, wherein the coating is made from a polymeric material containing a therapeutic substance.

36. The stent of claim **33**, wherein the strut includes a linear unitary segment extending into a curved or bent unitary segment, and wherein the unitary segment defined by the recessed volume is a part of the linear unitary segment of the strut.

37. The stent of claim **36**, wherein the curved or bent unitary segment includes a notch carved out from the surface of the strut.

38. The stent of claim **33**, wherein the strut has a rectangular, triangular, oval or circular cross-sectional shape.

39. A method of manufacturing a stent, comprising depositing a coating substance on a stent, the stent including a unitary strut segment having four sides including two pairs of opposing sides, each of the opposing sides having an outer surface, wherein the outer surfaces of each pair of opposing sides face in different directions, wherein each of the outer surfaces of one pair of opposing sides has a unitary segment defined by a recessed volume, and wherein the coating substance completely fills at least one recessed volume.

40. The method of claim **39**, wherein a width of each outer surface of the other pair of opposing sides is smaller in the unitary segment including the recessed volume than a width of a remaining portion of the unitary strut segment.

41. The method of claim **39**, wherein a thickness of each outer surface of the other pair of opposing sides is smaller in the unitary segment including the recessed volume than a thickness of a remaining portion of the unitary strut segment.

42. The method of claim **39**, wherein the coating substance includes a polymeric material.

43. The method of claim **39**, wherein the coating substance includes a therapeutic substance for the treatment of restenosis.

44. A method of manufacturing a stent, comprising depositing a coating on a stent, the stent including a strut having a unitary segment defined by a recessed volume disposed all the way around a circumference of the strut.

45. The method of claim **44**, wherein the coating includes a drug.

46. The method of claim **44**, wherein the strut has a rectangular, triangular, oval or circular cross-sectional shape.

47. The method of claim **44**, wherein an outer surface of the coating does not extend beyond an outer surface of the strut.

48. The method of claim **44**, wherein the strut includes a linear segment extending into a curved or bent segment, and

wherein the segment defined by the recessed volume is a part of the linear segment of the strut.

49. The method of claim **48**, wherein the curved or bent segment includes a notch carved out from the surface of the strut.

50. A radially expandable stent, comprising a unitary strut segment having four sides including two pairs of opposing sides, each of the opposing sides having an outer surface, wherein the outer surfaces of each pair of opposing sides face in different directions, wherein an outer dimension of each outer surface of one pair of opposing sides is less than an outer dimension of a remaining portion of the unitary strut segment so that each outer surface of the other pair of opposing sides has a unitary segment defined by a recessed volume, and wherein the recessed volume is at least partially filled with a coating substance.

51. The stent of claim **50**, wherein the coating substance includes a drug.

52. The stent of claim **50**, wherein the strut includes a linear segment extending into a curved or bent segment, and wherein the segment defined by the recessed volume is a part of the linear segment of the strut.

53. The stent of claim **52**, wherein the curved or bent segment includes a notch carved out from the surface of the strut.

54. A stent comprising:

a strut having a first segment, a second segment and a third segment located between the first and second segments, wherein the transverse cross-sectional area of the third segment is less than the transverse cross-sectional area of the first segment and the second segment such that a recessed volume of the strut is provided all the way around a circumference of the third segment, and wherein the strut includes a linear segment extending into a curved or bent segment, the first, second and third segments defining a part of the linear segment of the strut, wherein at least a segment of the curved or bent segment is smaller in thickness or width than the first or second segment of the strut; and

a coating disposed on the third segment of the strut, wherein the first and second segments of the strut are free of any coating,

wherein an outer surface of the coating does not extend beyond an outer surface of the first and second segments of the strut.

55. A method of manufacturing a stent, comprising:

depositing a coating on a stent, the stent including a strut having a first segment, a second segment and a third segment located between the first and second segments, wherein the transverse cross-sectional area of the third segment is less than the transverse cross-sectional area of the first segment and the second segment such that a recessed volume of the strut is provided all the way around a circumference of the third segment, and wherein the strut includes a linear segment extending into a curved or bent segment, the first, second and third segments defining a part of the linear segment of the strut, wherein at least a segment of the curved or bent segment is smaller in thickness or width than the first or second segment of the strut; and

removing the coating off of the first and second segments so that the coating remains on the third segment.

56. The method of claim **55**, wherein the coating includes a drug.

57. The method of claim **55**, wherein the strut has a rectangular, triangular, oval or circular cross-sectional shape.

58. The method of claim **55**, wherein an outer surface of the coating does not extend beyond an outer surface of the strut.

59. A method of manufacturing a stent, comprising:

depositing a coating on a stent, the stent including a strut segment having four sides including two pairs of opposing sides, each of the opposing sides having an outer surface, wherein the outer surfaces of each pair of opposing sides face in different directions, wherein an outer dimension of each outer surface of one pair of opposing sides is less than an outer dimension of a remaining portion of the strut segment so that each outer surface of the other pair of opposing sides has a segment defined by a recessed volume, and wherein the coating is carried by at least one recessed volume; and

removing the coating from each outer surface of the pair of opposing sides without the recessed volume so that the coating remains in the at least one recessed volume.

60. The method of claim **59**, wherein the coating includes a drug.

61. The method of claim **59**, wherein the strut has a rectangular, triangular, oval or circular cross-sectional shape.

62. The method of claim **59**, wherein an outer surface of the coating does not extend beyond the outer surfaces of the strut.

* * * * *

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(12) **United States Patent**
Limon

(10) **Patent No.: US 7,163,553 B2**
(45) **Date of Patent: Jan. 16, 2007**

(54) **INTRAVASCULAR STENT AND METHOD OF USE**

(75) Inventor: **Timothy A. Limon**, Cupertino, CA (US)

(73) Assignee: **Advanced Cardiovascular Systems, Inc.**, Santa Clara, CA (US)

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A61F 2/06 (2006.01)

(52) **U.S. Cl.** **623/1.15**

(58) **Field of Classification Search** 623/1.11–1.2, 623/1.35

See application file for complete search history.

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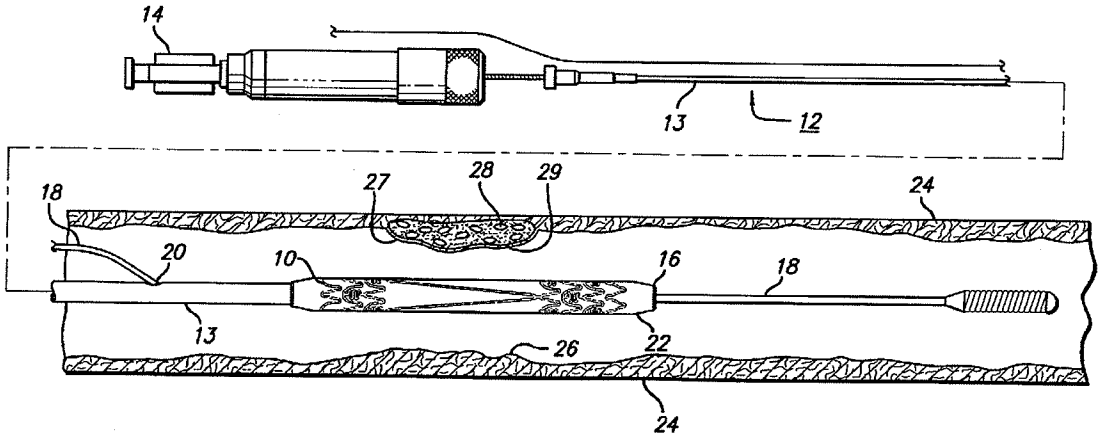
Primary Examiner—(Jackie) Tan-Uyen T. Ho
(74) *Attorney, Agent, or Firm*—Fulwider Patton LLP

(57) **ABSTRACT**

An expandable stent is implanted in a body lumen, such as a coronary artery, peripheral artery, or other body lumen for treating an area of vulnerable plaque. The invention provides for a an intravascular stent having a plurality of cylindrical rings connected by undulating links. The stent has a high degree of flexibility in the longitudinal direction, yet has adequate vessel wall coverage and radial strength sufficient to hold open an artery or other body lumen. A central section is positioned between distal and proximal sections and is aligned with the area of vulnerable plaque to enhance growth of endothelial cells over the fibrous cap of the vulnerable plaque to reinforce the area and reduce the likelihood of rupture.

63 Claims, 7 Drawing Sheets



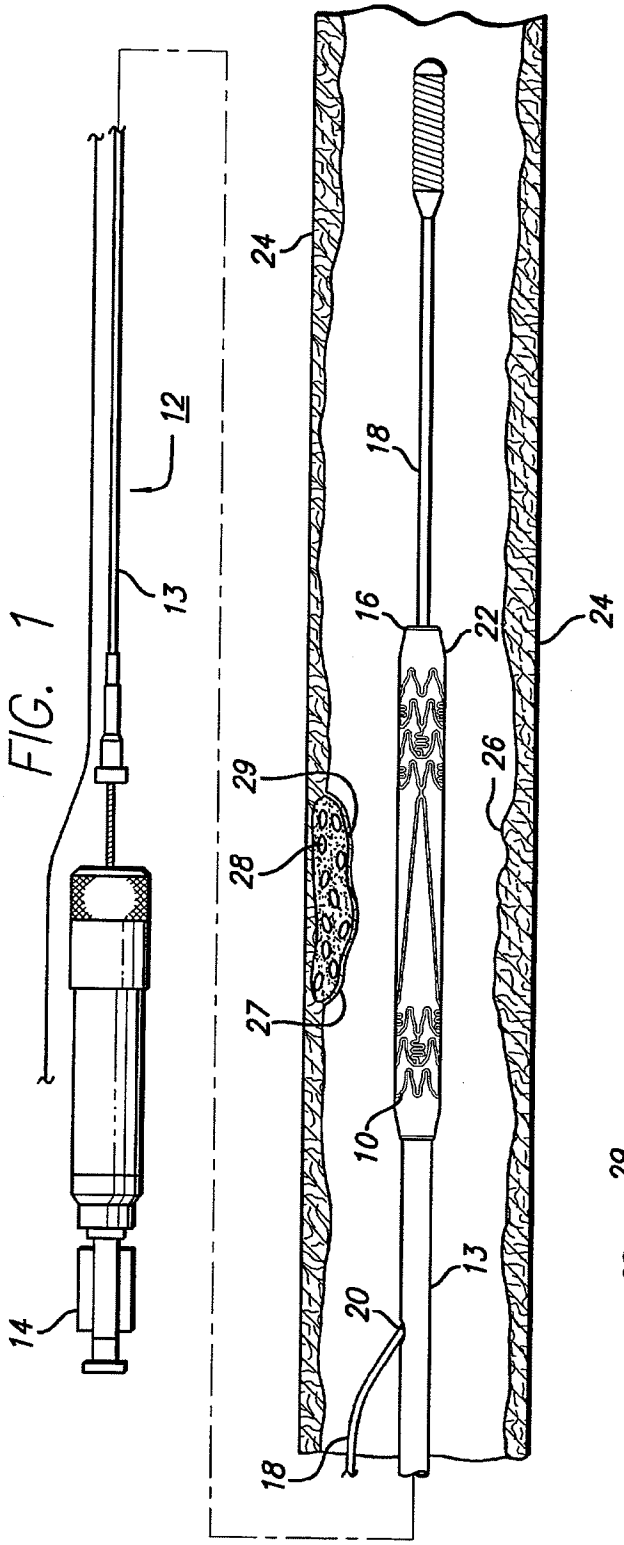


FIG. 1

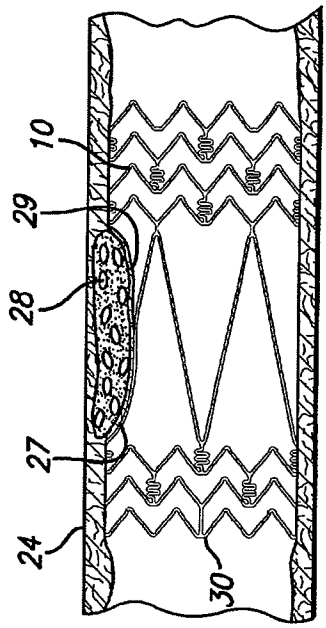


FIG. 3

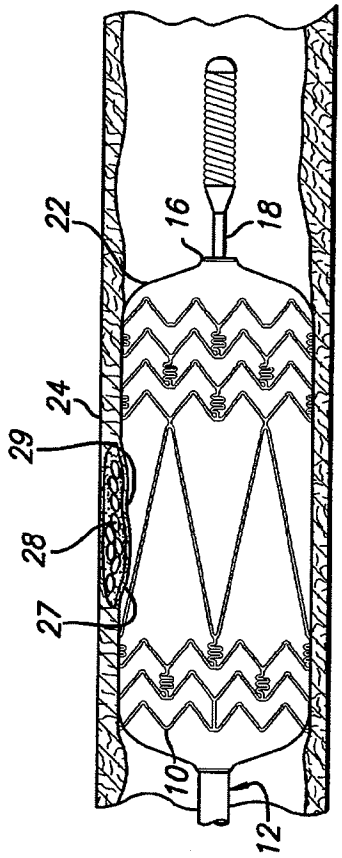


FIG. 2

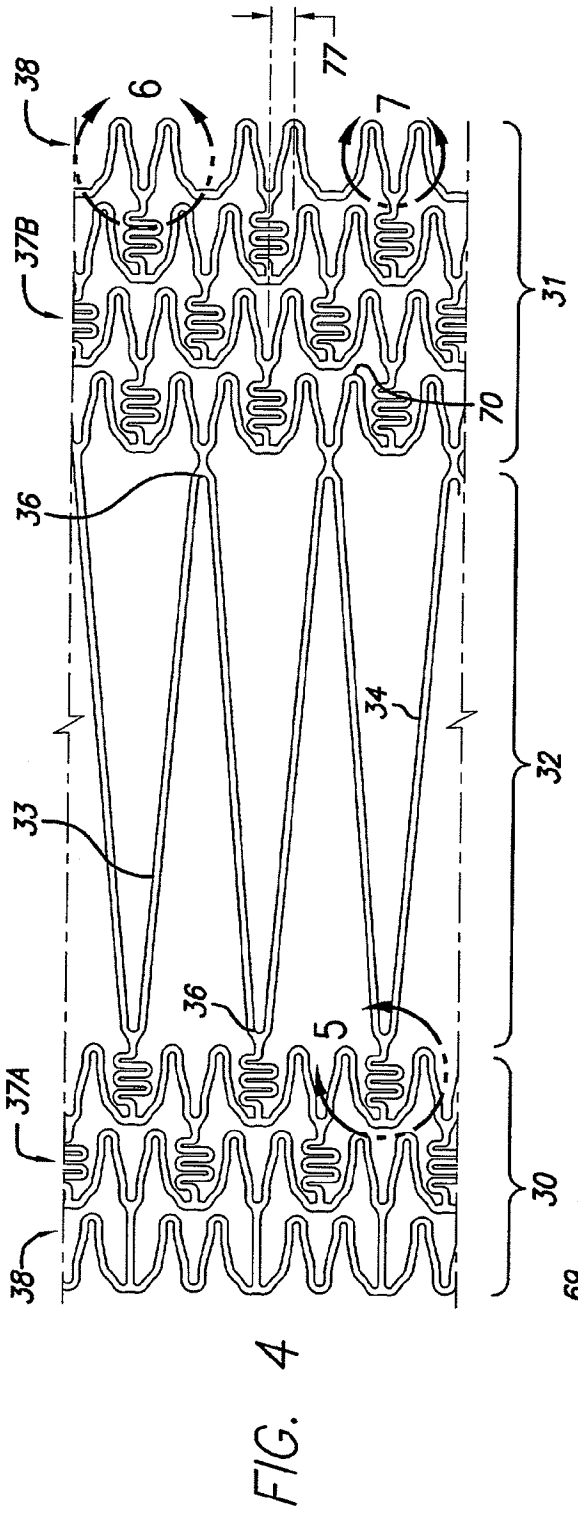


FIG. 4

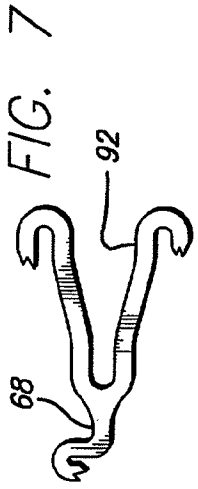


FIG. 7

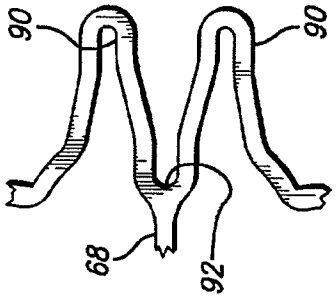


FIG. 6

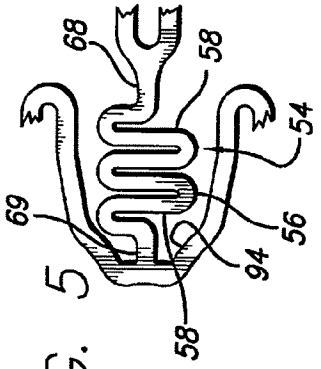


FIG. 5

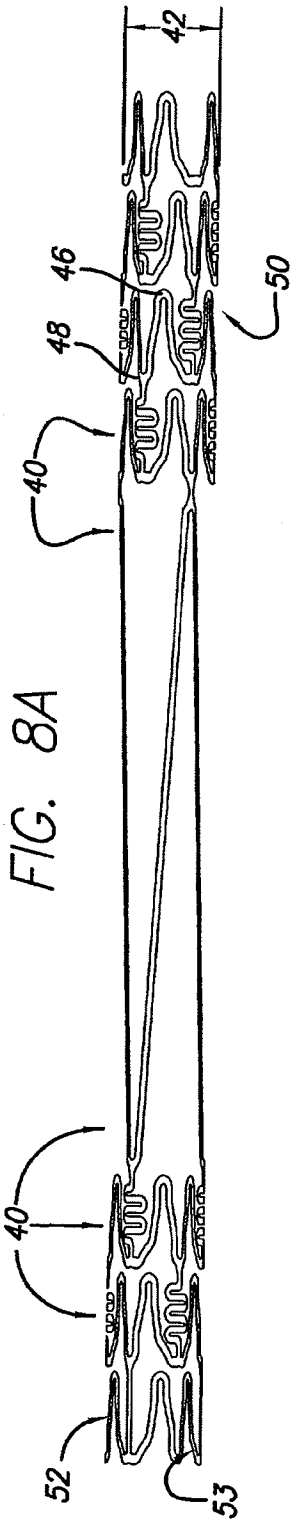


FIG. 8A

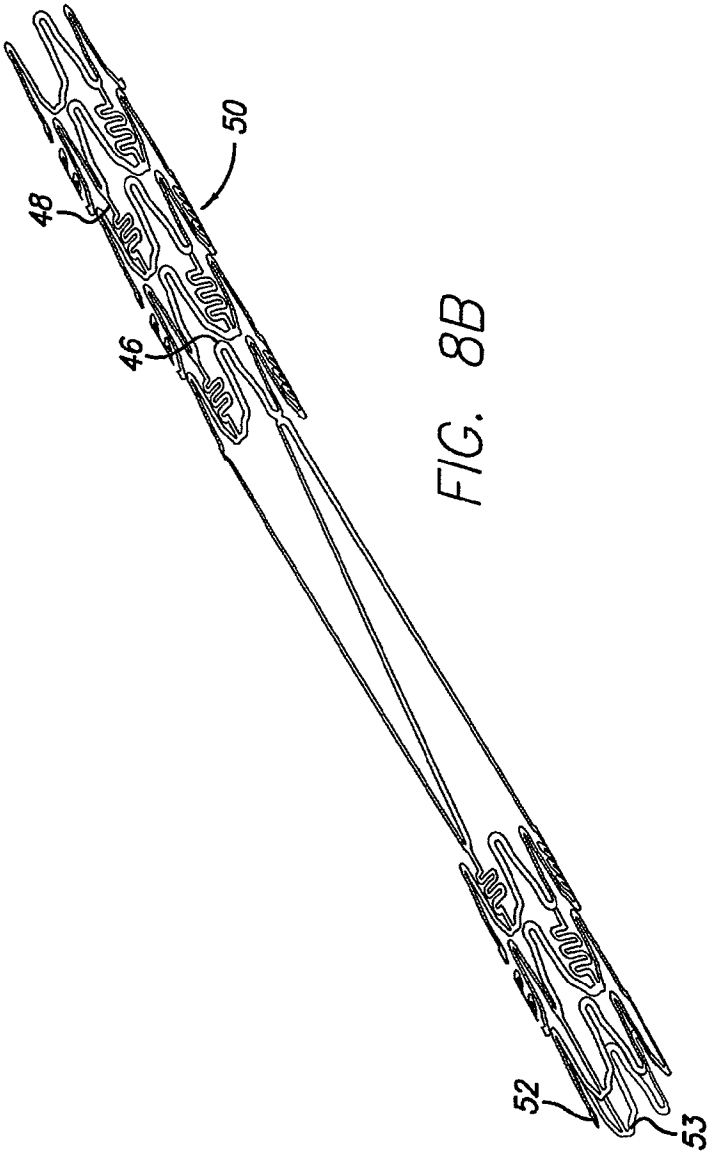


FIG. 8B

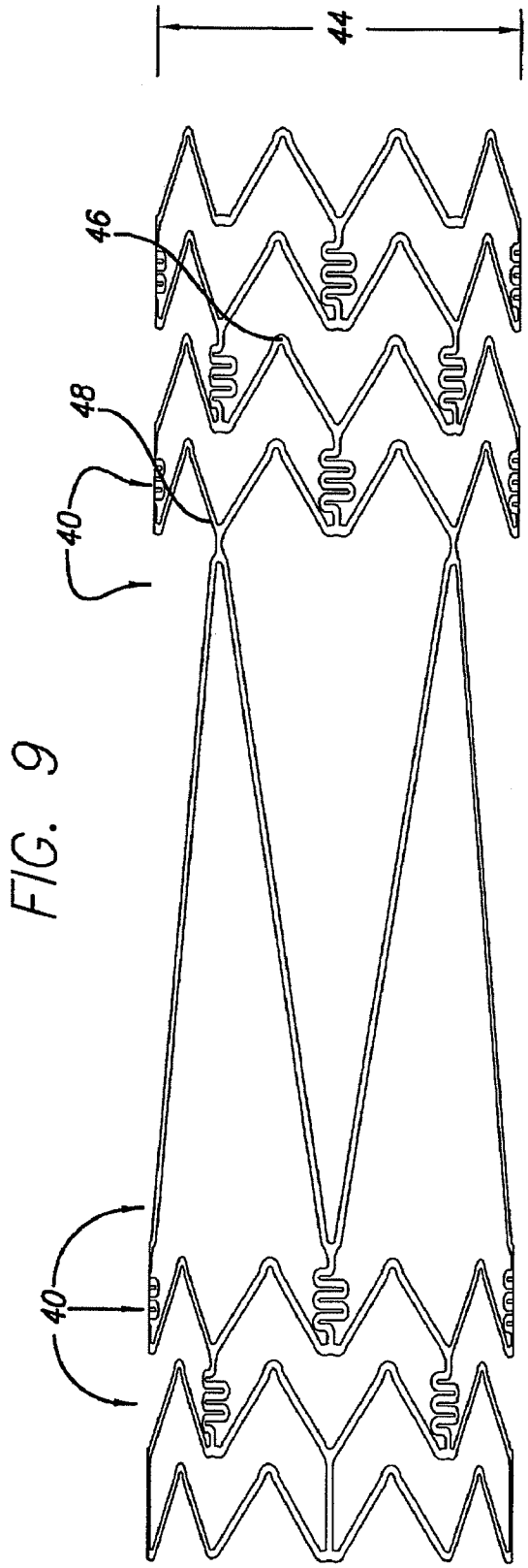


FIG. 9

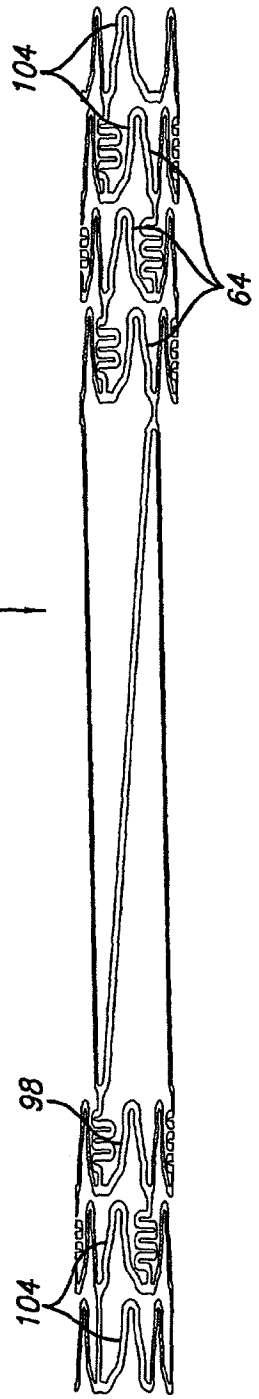


FIG. 10

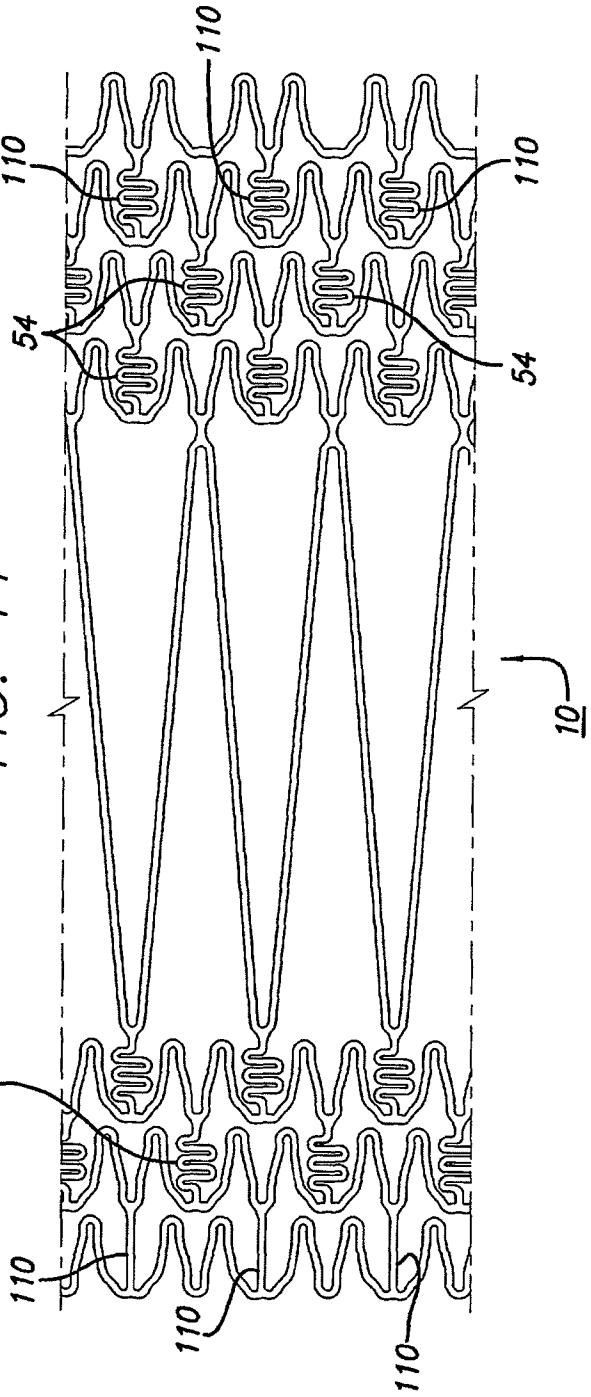


FIG. 11

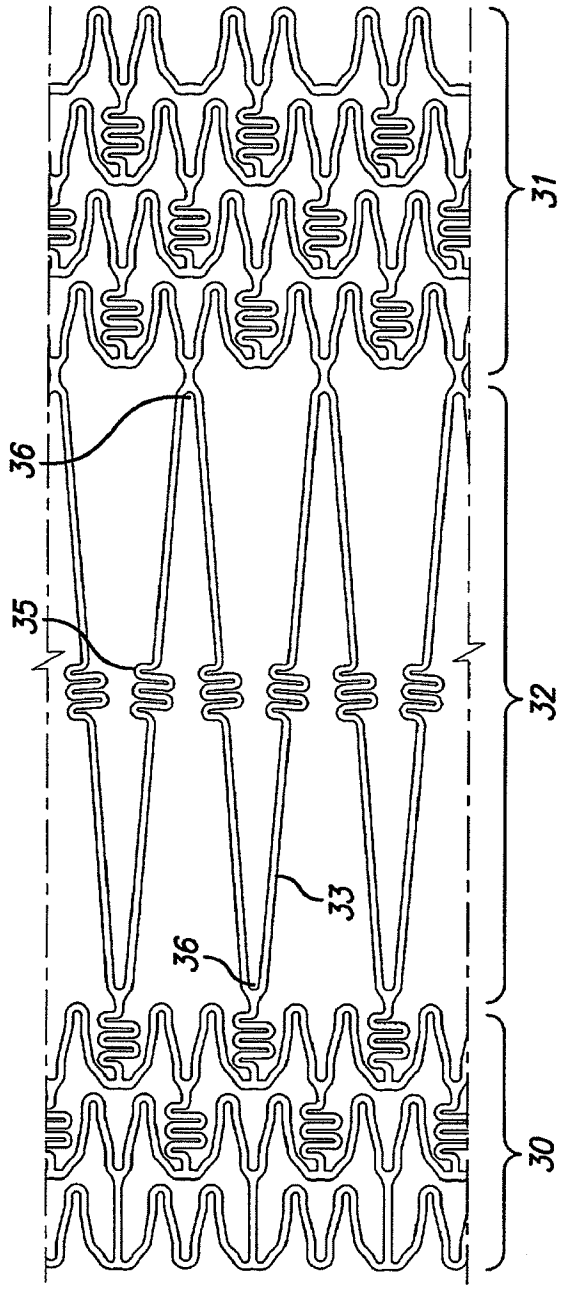


FIG. 12

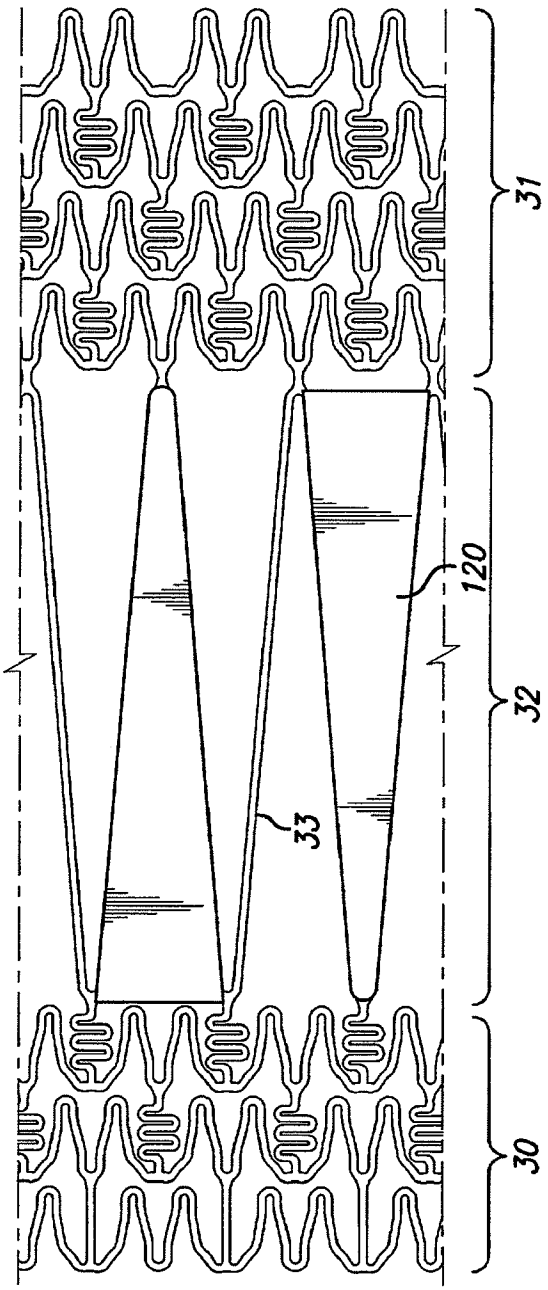


FIG. 13

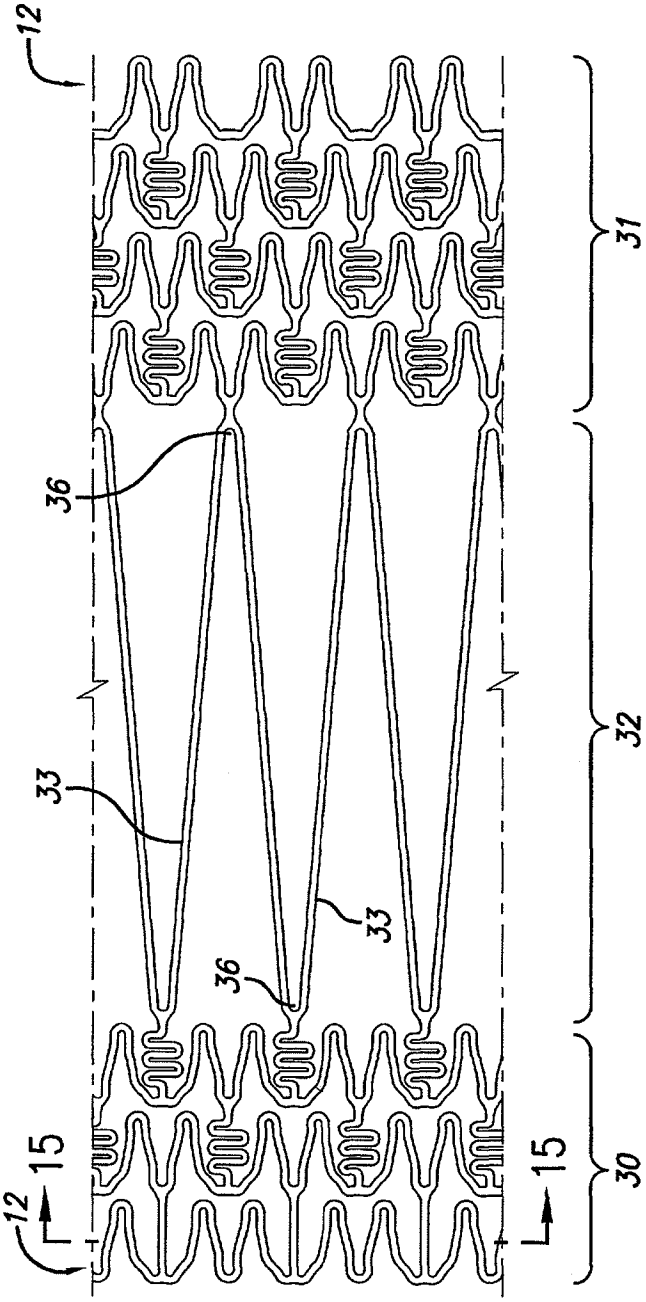


FIG. 14

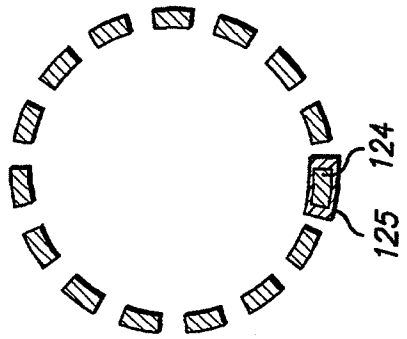


FIG. 15

INTRAVASCULAR STENT AND METHOD OF USE

BACKGROUND OF THE INVENTION

This invention relates to vascular repair devices, and in particular intravascular stents, which are adapted to be implanted into a patient's body lumen, such as a blood vessel or coronary artery, to maintain the patency thereof. Stents are particularly useful in the treatment of atherosclerotic stenosis in arteries and blood vessels.

Stents are generally tubular-shaped devices which function to hold open a segment of a blood vessel or other body lumen such as a coronary artery. They also are suitable for use to support and hold back a dissected arterial lining that can occlude the fluid passageway. At present, there are numerous commercial stents being marketed throughout the world. While some of these stents are flexible and have the appropriate radial rigidity needed to hold open a vessel or artery, there typically is a tradeoff between flexibility and radial strength.

Further, some coronary arteries may develop vulnerable plaque which may require treatment through stenting. What has been needed and heretofore unavailable is a stent which has a high degree of flexibility so that it can be advanced through tortuous passageways and can be readily expanded, and yet have the mechanical strength to hold open the body lumen or artery into which it is implanted and provide adequate vessel wall coverage at selected areas. What also has been needed is a stent that selectively reduces cell growth in one area, but enhances cell growth in other areas too, for example, cover the thin fibrous cap covering vulnerable plaque. The present invention satisfies these needs. The stent of the present invention has a high degree of flexibility making it possible to advance the stent easily through tortuous arteries, yet the stent has sufficient radial rigidity so that it can hold open an artery or other blood vessel, provide adequate vessel wall coverage, and enhance endothelial cell growth to reinforce the fibrous cover over any vulnerable plaque.

SUMMARY OF THE INVENTION

The present invention is directed to an intravascular stent which is highly flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but which is stiff and stable enough radially in its expanded condition to maintain the patency of a body lumen such as an artery when the stent is implanted therein. The novel stent pattern of the invention is particularly well suited for treating and repairing vulnerable plaque located in, for example, the coronary arteries.

The stent of the present invention generally includes a plurality of cylindrical rings that are interconnected to form a distal section and a proximal section, with a central section therebetween. The stent typically is mounted on a balloon catheter if it is balloon expandable or mounted on a catheter without a balloon if it is self expanding.

In one embodiment of the invention, the stent has a distal and proximal section formed of rings or cylindrical elements and links. The rings and links are configured so that the air to metal ratio is less than 90% and preferably less than about 80% thus providing good scaffolding and providing a more cylindrical lumen. A central section is formed of stent struts that join the distal and proximal sections together. The central section strut pattern is less dense than the rings and links pattern of the distal and proximal sections. This central section scaffolds less, making the lumen less cylindrical. In use, the central section is aligned with an area of vulnerable plaque so that as smooth muscle cell growth occurs after the stent is implanted, in an attempt to form a cylindrical lumen, the central section strut pattern promotes cell growth over the struts and hence over the fibrous cap of the vulnerable plaque. This cell layer acts to protect the vulnerable plaque from rupturing and possibly embolising in the artery. Comparatively, the rings and links pattern of the distal and proximal sections inhibit smooth muscle cell growth thereby maintaining a patent lumen for blood flow. Thus, the present invention stent promotes cell growth where needed, to cover and reinforce the vulnerable plaque area, and inhibits cell growth in other areas so that the lumen (artery) remains patent for maximum blood flow.

The central section of the stent includes struts that connect the distal and proximal section together. The central section struts can take different configurations and still function to hold open the vessel and promote cell growth. In one embodiment the struts are substantially straight and form a cylindrical zig-zag pattern. In another embodiment the central section struts have straight portions and curved portions which enhance stent flexibility. In yet another embodiment, the struts are curved or undulating. The length of the central section struts for all of the embodiments will depend on the length of the vulnerable plaque area to be repaired. If the plaque area is 6 to 8 mm in length, then the struts of the central section would be of a similar length or slightly longer. Typically, a coronary stent might be 18 mm long, therefore in one example, the central section struts would be 8 mm long and the distal and proximal sections each would be about 5 mm.

The cylindrical rings and links can have various configurations. In one embodiment, each of the cylindrical rings making up the stent have a proximal end and a distal end and a cylindrical plane defined by a cylindrical outer wall surface that extends circumferentially between the proximal end and the distal end of the cylindrical ring. The cylindrical rings are interconnected by at least one undulating link which attaches one cylindrical ring to an adjacent cylindrical ring. The undulating links are highly flexible and allow the stent to be highly flexible along its longitudinal axis. The undulating links are positioned substantially within the cylindrical plane of the outer wall surface of the cylindrical rings. The design of the highly flexible interconnecting members and their placement nested within a W-shaped member provides for uniform scaffolding and a high degree of vessel wall coverage at the proximal and distal sections.

The undulating links may take various configurations but in general have a undulating or serpentine shape. The undulating links can include bends connected by substantially straight portions wherein the substantially straight portions are substantially perpendicular to the stent longitudinal axis.

Not only do the undulating links that interconnect the cylindrical rings provide flexibility to the stent, but the positioning of the links also enhances the flexibility by allowing uniform flexibility when the stent is bent in any direction along its longitudinal axis. Further, the cylindrical rings are configured to provide flexibility to the stent in that portions of the rings can flex or bend and tip outwardly as the stent is delivered through a tortuous vessel.

In one embodiment of the invention, the cylindrical rings are connected by undulating links as described. In another embodiment, the rings are connected by substantially straight links, or continuation of straight links and undulat-

ing links. The number, amplitude and shape of the undulations in the links also can vary.

The cylindrical rings typically are formed of a plurality of peaks and valleys, where the valleys of one cylindrical ring are circumferentially offset from the valleys of an adjacent cylindrical ring. In this configuration, at least one undulating link attaches each cylindrical ring to an adjacent cylindrical ring so that the undulating links are positioned substantially within one of the valleys and it attaches the valley to an adjacent peak.

While the cylindrical rings and undulating links generally are not separate structures, they have been conveniently referred to as rings and links for ease of identification. Further, the cylindrical rings can be thought of as comprising a series of U's, W's and Y-shaped structures in a repeating pattern. Again, while the cylindrical rings are not divided up or segmented into U's, W's and Y's, the pattern of the cylindrical rings resemble such configuration. The U's, W's and Y's promote flexibility in the stent primarily by flexing and by tipping radially outwardly as the stent is delivered through a tortuous vessel.

The undulating links are positioned so that the undulating portion is within the curved part of the W-shaped portion which generally increases the amount of vessel wall coverage. Since the undulating portion does not substantially expand (if at all) when the stent is expanded, it will continue to provide good vessel wall coverage even as the curved part of the W-shaped portion spreads apart as the stent is expanded.

The cylindrical rings and the zig-zag shaped central section of the stent are plastically deformed when expanded when the stent is made from a metal that is balloon expandable. Typically, the balloon expandable stent is made from a stainless steel alloy or similar material.

Similarly, the cylindrical rings and the zig-zag struts of the central section of the stent expand radially outwardly when the stent is formed from a superelastic alloy, such as nickel titanium (NiTi). In the case of superelastic alloys, the stent expands upon application of a temperature change or when a stress is relieved, as in the case of a pseudoelastic phase change.

The number and location of undulating links that interconnect adjacent cylindrical rings can be varied as the application requires. Since the undulating links typically do not expand when the cylindrical rings of the stent expand radially outwardly, the links continue to provide flexibility and to also provide a scaffolding function to assist in holding open the artery. Importantly, the addition or removal of the undulating links has very little impact on the overall longitudinal flexibility of the stent. Each undulating link is configured so that it promotes flexibility whereas prior art links actually reduce flexibility of the stent.

Because of the undulating configuration of the links, the stent has a high degree of flexibility along the stent axis, which reduces the tendency of stent fishscaling. Stent fishscaling can occur when the stent is bent and portions of the stent project outward when the stent is in the unexpanded condition. The present invention undulating links reduce the likelihood of fishscaling.

In one embodiment, one or more sections of the stent are covered with a material such as PTFE or ePTFE. For example, the central section can be partially or completely covered with a sheath of material so that when the stent is implanted, the sheath aligns with and provides covering support for the vulnerable plaque.

The stent may be formed from a tube by laser cutting the pattern of cylindrical rings, undulating links, and central section struts in the tube. The stent also may be formed by laser cutting a flat metal sheet in the pattern of the struts, cylindrical rings, and links, and then rolling the pattern into the shape of the tubular stent and providing a longitudinal weld to form the stent.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an elevational view, partially in section, of a stent embodying features of the invention and which is mounted on a rapid-exchange delivery catheter and positioned within an artery.

FIG. **2** is an elevational view, partially in section, similar to that shown in FIG. **1** wherein the stent is expanded within the artery, so that the stent embeds within the arterial wall.

FIG. **3** is an elevational view, partially in section, showing the expanded stent implanted within the artery after withdrawal of the rapid-exchange delivery catheter.

FIG. **4** is a plan view of a flattened stent of the invention which illustrates the pattern of the stent shown in FIGS. **1–3**.

FIG. **5** is an enlarged view of a portion of the stent shown in FIG. **4** depicting an undulating link connecting portions of adjacent cylindrical rings.

FIG. **6** is an enlarged sectional view of FIG. **4** depicting several peaks of a cylindrical ring.

FIG.**7** is an enlarged sectional view of FIG. **4** depicting a Y-shaped portion of the cylindrical ring.

FIG. **8**A is a side view of a stent embodying features of the invention in an unexpanded state.

FIG. **8**B is a perspective view of the stent of FIG. **8**A depicting the cylindrical wall defined by each cylindrical ring.

FIG. **9** is a perspective view of the stent of FIG. **8**A in an expanded condition.

FIG. **10** is a side view of the stent depicting cylindrical rings at the end of the stent having a thicker cross-section than the rings at the center of the stent.

FIG. **11** is a plan view of a flattened stent of the invention illustrating a combination of undulating links and straight links.

FIG. **12** is a plan view of a flattened stent depicting undulating struts in the central section.

FIG. **13** is a plan view of a flattened stent depicting a covering over portions of the stent.

FIG. **14** is a plan view of a flattened stent having a drug coating on selected portions.

FIG. **15** is a cross-sectional view taken along lines **15—15** depicting the drug coating on a portion of the stent.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention stent improves on existing stents by providing a longitudinally flexible stent having a uniquely designed pattern and novel interconnecting members. In addition to providing longitudinal flexibility, the stent of the present invention also provides radial rigidity and a high degree of scaffolding of a vessel wall at the stent ends and less scaffolding in the central section to intentionally promote smooth muscle cell growth. The design of the highly flexible interconnecting members and their placement nested within a W-shaped member provides for uniform scaffolding and a high degree of vessel wall coverage while the struts of the central section provide comparatively minimal vessel wall coverage.

Turning to the drawings, FIG. **1** depicts the present invention stent **10** mounted on a catheter assembly **12** which

is used to deliver the stent and implant it in a body lumen, such as a coronary artery, peripheral artery, or other vessel or lumen within the body. The catheter assembly includes a catheter shaft **13** which has a proximal end **14** and a distal end **16**. The catheter assembly is configured to advance through the patient's vascular system by advancing over a guide wire by any of the well known methods of an over the wire system (not shown) or a well known rapid exchange catheter system, such as the one shown in FIG. **1**.

Catheter assembly **12** as depicted in FIG. **1** is of the well known rapid exchange type which includes an RX port **20** where the guide wire **18** will exit the catheter. The distal end of the guide wire **18** exits the catheter distal end **16** so that the catheter advances along the guide wire on a section of the catheter between the RX port **20** and the catheter distal end **16**. As is known in the art, the guide wire lumen which receives the guide wire is sized for receiving various diameter guide wires to suit a particular application. The stent is mounted on the expandable member **22** (balloon) and is crimped tightly thereon so that the stent and expandable member present a low profile diameter for delivery through the arteries.

As shown in FIG. **1**, a partial cross-section of an artery **24** is shown with a small amount of plaque **26** that has been previously treated by an angioplasty or other repair procedure. Stent **10** of the present invention is used to repair a diseased or damaged arterial wall which may include the plaque **26** as shown in FIG. **1**, or vulnerable plaque **27** which is commonly found in the coronary arteries, peripheral arteries and other vessels. Vulnerable plaque consists of a thrombogenic lipid **28** that is covered by a thin fibrous cap **29**. The stent of the invention is configured to repair the vessel having both plaque and vulnerable plaque.

In a typical procedure to implant stent **10**, the guide wire **18** is advanced through the patient's vascular system by well known methods so that the distal end of the guide wire is advanced past the plaque or diseased area **26**. Prior to implanting the stent, the cardiologist may wish to perform an angioplasty procedure or other procedure (i.e., atherectomy) in order to open the vessel and remodel the diseased area. Thereafter, the stent delivery catheter assembly **12** is advanced over the guide wire so that the stent is positioned in the target area. The expandable member or balloon **22** is inflated by well known means so that it expands radially outwardly and in turn expands the stent radially outwardly until the stent is apposed to the vessel wall. The expandable member is then deflated and the catheter withdrawn from the patient's vascular system. The guide wire typically is left in the lumen for post-dilatation procedures, if any, and subsequently is withdrawn from the patient's vascular system. As depicted in FIGS. **2** and **3**, the balloon is fully inflated with the stent expanded and pressed against the vessel wall, and in FIG. **3**, the implanted stent remains in the vessel after the balloon has been deflated and the catheter assembly and guide wire have been withdrawn from the patient.

The stent **10** serves to hold open the artery after the catheter is withdrawn, as illustrated by FIG. **3**. Due to the formation of the stent from an elongated tubular member, the undulating components of the stent are relatively flat in transverse cross-section, so that when the stent is expanded, it is pressed into the wall of the artery and as a result does not interfere with the blood flow through the artery. The stent is pressed into the wall of the artery and will eventually be covered with smooth muscle cell growth which further minimizes blood flow interference. The undulating portion of the stent provides good tacking characteristics to prevent stent movement within the artery.

In keeping with the present invention, FIGS. **4–11** depict stent **10** in various configurations. Turning to FIG. **4**, stent **10** is shown in a flattened condition so that the pattern can be clearly viewed, even though the stent is never in this form. The stent is typically formed from a tubular member, however, it can be formed from a flat sheet such as shown in FIG. **4** and rolled into a cylindrical configuration.

The stent of the present invention is particularly useful in treating vulnerable plaque **27** which generally comprises a thrombogenic lipid **28** that has accumulated and is covered by a thin fibrous cap **29**. As shown in FIGS. **4–11**, the stent is designed to have three sections, a distal section **30**, a proximal section **31**, and a central section **32**. The distal section and the proximal section typically include cylindrical rings **40** which are connected by one or more links **54**, both of which will be further described herein. With respect to the central section **32**, it is designed to be aligned with the vulnerable plaque in the area of the fibrous cap so that after the stent is implanted, smooth muscle cells will accumulate and readily grow over the central section thereby reinforcing the fibrous cap and preventing rupture, and thence emboli in the form of the released thrombogenic lipid. The central section **32** includes struts **33** which are depicted as straight struts **34**, however, the struts can have undulating member **35** as shown in FIG. **12**. The straight struts **34** or the undulating struts **35** are connected by apices **36**, which are typically curved to enhance stent expansion. Together the struts and apices form the connection between the distal section **30** and the proximal section **31**. It has been shown through empirical data that increasing the number of struts per cross-section provides an associated drop in neointimal thickening after a short period of time. In other words, the distal section **30** and the proximal section **32** have a higher density of struts in the form of cylindrical rings and links than does the central section **32** having struts **33**. Based on the empirical data, the struts **33** will promote development of neointimal thickness along the struts which are aligned with the fibrous cap, thereby providing a thickening of cell growth over the fibrous cap and reinforcing the area in order to prevent rupture of the thrombogenic lipid into an artery or other vessel.

The stent **10** of the present invention also can be described has having a first strut pattern **37A** and a second strut pattern **37B** in the distal section **30** and the proximal section **31**, respectively. A third strut pattern **37C** is formed in the central section and includes struts **33** which can either be straight **34** or undulating struts **35**. The straight struts and the undulating struts are connected by apices **36** and the struts and apices together form the connection between the first strut pattern in the distal section **30** and the second strut pattern in the proximal section **31**.

With respect to the structure of the cylindrical rings and links, virtually any pattern is acceptable as long as the pattern of struts are more dense than the strut pattern in the central section **32**. Typically, the rings are in the form generally of a zig-zag pattern **38** that can easily expand radially outwardly or compress radially inwardly. Thus, as described immediately below, several examples of cylindrical rings **40** and links **54** are described, however, other patterns are envisioned that would perform equally as well in inhibiting growth of smooth muscle cells at the stent proximal and distal ends and more specifically in the distal section **30** and the proximal section **31**.

As shown in FIGS. **4–11**, stent **10** is made up of a plurality of cylindrical rings **40** which extend circumferentially around the stent when it is in a tubular form (see FIG. **8**). The stent has a delivery diameter **42** as shown in FIG. **8**, and an

implanted diameter **44** as shown in FIG. **9**. Each cylindrical ring **40** has a cylindrical ring proximal end **46** and a cylindrical ring distal end **48**. Typically, since the stent is laser cut from a solid tube there are no discreet parts such as the described cylindrical rings. However, it is beneficial for identification and reference to various parts to refer to the cylindrical rings and the following parts of the stent.

Each cylindrical ring **40** defines a cylindrical plane **50** which is a plane defined by the proximal and distal ends **46**, **48** and the circumferential extent as the cylindrical ring travels around the cylinder. Each cylindrical ring includes cylindrical outer wall surface **52** which defines the outermost surface of the stent, and cylindrical inner wall surface **53** which defines the innermost surface of the stent. Cylindrical plane **50** follows the cylindrical outer wall surface.

In keeping with the invention, undulating link **54** is positioned within cylindrical plane **50**. The undulating links connect one cylindrical ring to an adjacent cylindrical ring and provide overall longitudinal flexibility to the stent due to their unique construction. The flexibility of undulating links derives in part from bends **56** connected to straight portions **58** wherein the straight portions are substantially perpendicular to the longitudinal axis of the stent. Thus, as the stent is being delivered through a tortuous vessel, such as a coronary artery, the bends **56** and straight portions **58** of the undulating links will permit the stent to flex in the longitudinal direction which substantially enhances delivery of the stent to the target site. The number of bends and straight portions can be increased or decreased from that shown, to achieve differing flexibility constructions. With the straight portions being substantially perpendicular to the stent longitudinal axis, the undulating link acts like a hinge to provide flexibility. A straight link that is parallel to the stent axis typically is not flexible and does not add to the flexibility of the stent.

Cylindrical rings **40** can be nested such that adjacent rings slightly overlap in the longitudinal direction so that one ring is slightly nested within the next ring and so on. The degree of nesting is dictated primarily by the length of each cylindrical ring, the number of undulations in the rings, the thickness of the struts that make up the rings, and the radius of curvature, all in conjunction with the crimped or delivery diameter of the stent. If the rings are substantially nested one within the other, it may be difficult to crimp the stent to an appropriate delivery diameter without the various struts overlapping. It is also contemplated that the rings are slightly nested even after the stent is expanded, which enhances vessel wall coverage. In some circumstances, it may not be desirable to nest one ring within the other, which is also contemplated by the invention.

Referring to FIGS. **4–11**, the stent **10** can be described more particularly as having a plurality of peaks **70** and valleys **72**. Although the stent is not divided into separate elements, for ease of discussion references to peaks and valleys is appropriate. The number of peaks and valleys, sometimes referred to as crowns, can vary in number for each ring depending upon the application. Thus, for example, if the stent is to be implanted in a coronary artery, a lesser number of peaks and valleys (or crowns) are required than if the stent is implanted in a peripheral artery, which has a larger diameter than a coronary artery. As can be seen in FIG. **4**, peaks **70** are in phase **74**, meaning that the peaks **70** are substantially aligned along the longitudinal axis of the stent. It may be desirable under certain circumstances to position peaks **70** so that they are out of phase (not shown), that is, the peaks of one ring would be circumferentially offset from the peaks of an adjacent ring. As shown in FIG. **4**, the peaks are circumferentially offset **77** from the valleys and from the undulating link **54**. Positioning the peaks, valleys, and undulating links in this manner, provides a stent having uniform expansion capabilities, high radial strength, a high degree of flexibility, and sufficient wall coverage to support the vessel.

Referring to FIGS. **5–7**, the stent of the invention can be described as having cylindrical rings formed of U-shaped portions **90**, Y-shaped portions **92**, and W-shaped portions **94**. Again, while the stent is generally laser cut from a solid tube and it typically has no discreet parts, for ease of identification the stent of the invention also can be referred to as having U-, Y-, and W-shaped portions. The U-shaped portions have not supporting structure attached thereto. The Y-shaped portions, at their base, or apex, have arm **68** extending therefrom and attached to undulating link **54**. The W portion has at its base or curve portion arm **69** which attaches at the other end of the undulating link. The length of the arms attaching the links to the rings can vary. Importantly, the arms should be sized in conjunction with the undulating link so that the link is properly positioned in the W-shaped portion. Preferably, undulating link **54** is contained within W-shaped portion **94**, which should be wide enough to accommodate the undulating link when the stent is crimped so that no portion of the undulating link and the W-portion overlap. Preferably, the undulating link and the W-shaped portion are in the same cylindrical plane **50** as defined by the cylindrical outer wall surface **52** and the cylindrical inner wall surface **53**.

In one aspect of the invention, the stent is formed so that the struts **98** (FIG. **10**) have variable thickness along the stent length. As one example, it is contemplated that struts **104** at the ends of the stent may be thicker than the struts **106** in the center of the stent for purposes for radiopacity and to counter balloon expansion. When the balloon first inflates, the balloon ends have a tendency to inflate at a faster rate than the balloon center, however, with thicker struts at the stent ends the balloon, and hence the stent, will expand more uniformly.

As described above, it is also contemplated that more or fewer undulating links **54** will be positioned between adjacent cylindrical rings **40**. It is also contemplated, in order to increase stent stability, that straight links **110**, as shown in FIG. **11**, in addition to undulating links **54**, connect adjacent cylindrical rings. The straight links will provide stability and assist in preventing stent foreshortening, as do the undulating links. The straight links allow the rings to be crimped or compressed more tightly at the stent ends which aids in delivering the stent through tortuous arteries. Further, the straight links may provide more rigidity in a localized area, such as at the stent ends, such that it may be desirable to incorporate more straight links between the cylindrical rings at the stent ends, than in the center of the stent.

In one important aspect of the invention, after stent **10** is implanted in a coronary artery, or other vessel, because of its novel design, the cylindrical rings **40** have the ability to flex radially as the vessel pulsates when blood pumps through it. Likewise, because of the novel and unique design of undulating links **54**, as the vessel moves and pulsates from the pumping blood, the stent can flex longitudinally. The radial and longitudinal flexing of the stent reduces the likelihood that the stent will cause injury to the intima of a coronary artery, which also may have a tendency to reduce the likelihood of restenosis.

Any portion of the disclosed stent can be made from a metal alloy or from a polymer. For example, the cylindrical rings can be made from a metal alloy while the connecting

links can be made from a metal alloy or a polymer. Typically, if the links are made from a polymer, the stent will be more longitudinally flexible than if the links were made from a metal alloy. Also, the central section struts can be made from either a metal alloy or a polymer.

Exemplary of the metallic material used in forming the cylindrical rings and links of the stent is stainless steel, titanium, nickel titanium, tantalum, gold, cobalt-chromium, platinum, palladium, and iradium. Other metals, metal alloys and polymers may also be used to form the present invention stent.

Exemplary of the biocompatible polymer material used in forming the central section struts, the rings, or the links includes the group of polymers consisting of polyurethanes, polyetherurethanes, polyesterurethanes, silicone, thermoplastic elastomer (C-flex), polyether-amide thermoplastic elastomer (Pebax), fluoroelastomers, fluorosilicone elastomer, styrene-butadiene rubber, butadiene-styrene rubber, polyisoprene, neoprene (polychloroprene), ethylene-propylene elastomer, chlorosulfonated polyethylene elastomer, butyl rubber, polysulfide elastomer, polyacrylate elastomer, nitrile rubber, a family of elastomers composed of styrene, ethylene, propylene, aliphatic polycarbonate polyurethane, polymers augmented with antioxidants, polymers augmented with image enhancing materials, polymers having a proton (H+) core, polymers augmented with protons (H+), butadiene and isoprene (Kraton) and polyester thermoplastic elastomer (Hytrel), polyethylene, PLA, PGA, and PLGA.

It may be desirable to provide a cover on one or more portions of the stent **10** of the present invention. As shown in FIG. **13**, for example, stent cover **120** covers portions of the central section which will come in contact with the fibrous cap. The stent cover is used to strengthen and support the area in the fibrous cap to prevent rupture. Since only a portion of the central section is covered, the remaining open sections will develop smooth muscle cell growth over the central section struts **33** thereby further supporting the area around the vulnerable plaque **27**. Portions of the distal section and proximal section **30,31** also can be covered with stent cover **120**. The stent cover can include materials such as PTFE or ePTFE, or their equivalent. The stent cover can be attached to the stent by various means including adhesives or laser bonding. Further, it is desirable that the stent cover have at least some elastic properties so that as the stent expands from a delivered diameter to an implanted diameter, the stent cover does not distort or prevent stent expansion.

The stent **10** may also be used in connection with a therapeutic agent to perform a variety of functions, from preventing blood clots to promoting healing. As an example and as shown in FIGS. **14** and **15**, an active agent coated **125** on struts **124** in the distal and/or proximal sections **30,31** can inhibit the activity of endothelial cells. Similarly, an active agent coated on selective cylindrical rings **12** can also inhibit the activity of smooth muscle cells. More specifically, the active agent is aimed at inhibiting abnormal or inappropriate migration and proliferation of smooth muscle cells. The active agent can also include any substance capable of exerting a therapeutic or prophylactic effect in the practice of the present invention. The agent can also be for enhancing wound healing in a vascular site or improving the structural and elastic properties of the vascular site. The dosage or concentration of the active agent required to produce a favorable therapeutic effect should be less than the level at which the active agent produces toxic effects and greater than the level at which non-therapeutic results are obtained. The dosage or concentration of the active agent required to inhibit the desired cellular activity of the vascular region can depend upon factors such as the particular circumstances of the patient; the nature of the trauma; the nature of the therapy desired; the time over which the ingredient administered resides at the vascular site; and if other therapeutic agents are employed, the nature and type of the substance or combination of substances. Therapeutic effective dosages can be determined empirically, for example by infusing vessels from suitable animal model systems and using immunohistochemical, fluorescent or electron microscopy methods to detect the agent and its effects, or by conducting suitable in vitro studies. Standard pharmacological test procedures to determine dosages are understood by one of ordinary skill in the art.

Importantly, any use of a therapeutic agent on the stent distal and proximal sections **30,31** to inhibit cell growth, must be balanced with the objective of the central section **32** to promote cell growth over the vulnerable plaque area **27**.

Examples of therapeutic agents include rapamycin, actinomycin D (ActD), or derivatives and analogs thereof ActD is manufactured by Sigma-Aldrich, 1001 West Saint Paul Avenue, Milwaukee Wis. 53233, or COSMEGEN, available from Merck. Synonyms of actinopmycin D include dactinomycin, actinomycin IV, actinomycin 11, actinomycin X1, and actinomycin C1. Examples of agents include other antiproliferative substances as well as antineoplastic, antinflammatory, antiplatelet, anticoagulant, antifibrin, antithomobin, antimitotic, antibiotic, and antioxidant substances. Examples of antineoplastics include taxol (paclitaxel and docetaxel). Examples of antiplatelets,, anticoagulants, antifibrins, and antithrombins include sodium heparin, low molecular weight heparin, hirudin, argatroban, forskolin, vapiprost, prostacyclin andprostacyclin analogs, dextran, D-phe-pro-arg-chloromethylketone (synthetic antithrombin), dipyridamole, glycoprotein, llb/llla platelet membrane receptor antagonist, recombinant hirudin, thrombin inhibitor (available from Biogen), and 7E-3B® (an antiplatelet drug from Centocore). Examples of antimitotic agents include methotrexate, azathioprine, vincristine, vinblastine, fluorouracil, adriamycin, and mutamycin. Examples of cytostatic or antiproliferative agents include angiopeptin (a somatostatin analog from Ibsen), angiotensin converting enzyme inhibitors such as Captopril (available from Squibb), Cilazapril (available from Hoffman-LaRoche), or Lisinopril (available from Merck); calcium channel blockers (such as Nifedipine), colchicine fibroblast growth factor (FGF) antagonists, fish oil (omega 3-fatty acid), histamine antagonist, Lovastatin (an inhibitor of HMG-CoA reductase, a cholesterol lowering drug from Merck), monoclonal antibodies (such as PDGF receptors), nitroprusside, phosphodiesterase inhibitors, prostaglandin inhibitor (available from Glazo), Seramin (a PDGF antagonist), serotonin blockers, steroids, thioprotease inhibitors, triazolopyrimidine (a PDGF antagonist), and nitric oxide. Other therapeutic substances or agents which may be appropriate include alpha-interferon, genetically engineered epithelial cells, and dexamethasone.

The stent **10** of the present invention can be made in many ways. One method of making the stent is to cut a thin-walled tubular member, such as stainless steel tubing to remove portions of the tubing in the desired pattern for the stent, leaving relatively untouched the portions of the metallic tubing which are to form the stent. In accordance with the invention, it is preferred to cut the tubing in the desired pattern by means of a machine-controlled laser as is well known in the art.

After laser cutting the stent pattern the stents are preferably electrochemically polished in an acidic aqueous solution such as a solution of ELECTRO-GLO#300, sold by

ELECTRO-GLO Co., Inc. in Chicago, Ill., which is a mixture of sulfuric acid, carboxylic acids, phosphates, corrosion inhibitors and a biodegradable surface active agent. Other electropolishing solutions are well known in the art. The stents may be further treated if desired, for example by applying a biocompatible coating.

Other methods of forming the stent of the present invention can be used, such as chemical etching; electric discharge machining; laser cutting a flat sheet and rolling it into a cylinder; and the like, all of which are well known in the art at this time.

The stent of the present invention also can be made from metal alloys other than stainless steel, such as shape memory alloys. Shape memory alloys are well known and include, but are not limited to, nickel titanium and nickel/titanium/vanadium. Any of the shape memory alloys can be formed into a tube and laser cut in order to form the pattern of the stent of the present invention. As is well known, the shape memory alloys of the stent of the present invention can include the type known as thermoelastic martensitic transformation, or display stress-induced martensite. These types of alloys are well known in the art and need not be further described here.

Importantly, a stent formed of shape memory alloys, whether the thermoelastic or the stress-induced martensite-type, can be delivered using a balloon catheter of the type described herein, or in the case of stress induced martensite, be delivered via a catheter without a balloon or a sheath catheter.

While the invention has been illustrated and described herein, in terms of its use as an intravascular stent, it will be apparent to those skilled in the art that the stent can be used in other body lumens. Further, particular sizes and dimensions, number of peaks per ring, materials used, and the like have been described herein and are provided as examples only. Other modifications and improvements may be made without departing from the scope of the invention.

What is claimed:

1. A method of implanting an intravascular stent for repairing a body lumen having vulnerable plaque of a predetermined length, comprising:

providing a catheter having a proximal end and a distal end and an expandable member adjacent the distal end;

providing an intravascular stent, mounted on the expandable member, the stent having a distal section, a proximal section, and a central section positioned between the distal section and the proximal section, the central section having a plurality of struts connected by apices to form a substantially zig zag pattern around the circumference of the stent in the central section;

the distal section and the proximal section having cylindrical rings having a first longitudinal length, and the central section having a cylindrical ring having a second longitudinal length at least as long as the predetermined length of the vulnerable plaque, the first longitudinal length being shorter than the second longitudinal length;

the central section struts being arranged in a substantially uniform repeating pattern forming a single ring;

the central section struts having a substantially uniform air to metal ratio;

inserting the catheter into the vascular system and advancing the catheter distal end so that the stent is positioned in a body lumen to be repaired;

aligning the stent in the body lumen so that the central section substantially aligns with the area of vulnerable plaque;

inflating the expandable member and implanting the stent in the body lumen; and

deflating the expandable member and withdrawing the catheter from the vascular system.

2. A flexible intravascular stent for use in a body lumen, comprising:

a distal section, a proximal section, and a central section positioned therebetween;

the distal section and the proximal section each having a plurality of interconnected cylindrical rings, each cylindrical ring having a first delivery diameter and a second expanded diameter;

each cylindrical ring having a proximal end and a distal end and a cylindrical wall extending circumferentially between the proximal end and the distal end of the cylindrical ring;

the distal section and the proximal section having cylindrical rings having a first longitudinal length, and the central section having a cylindrical ring having a second longitudinal length, the first longitudinal length being shorter than the second longitudinal length;

at least one undulating link attaching each cylindrical ring to an adjacent cylindrical ring, the undulating links being positioned substantially within the cylindrical wall of the cylindrical ring;

the central section having a plurality of struts connected by apices and extending around the circumference of the central section, the struts and apices connecting the distal section to the proximal section, the central section struts being arranged in a substantially uniform repeating zig zag pattern forming a single central ring; and

the central section having a substantially uniform air to metal ratio.

3. The stent of claim **2**, wherein the central section struts have a straight configuration.

4. The stent of claim **2**, wherein the central section struts have a substantially curved configuration.

5. The stent of claim **2**, wherein the central section struts have a substantially straight section and a substantially curved section.

6. The stent of claim **2**, wherein at least one undulating link comprises at least one bend connected to a substantially straight portion, the substantially straight portion being substantially perpendicular to the stent longitudinal axis.

7. The stent of claim **6**, wherein the substantially straight portion of the at least one undulating link is perpendicular to the stent longitudinal axis when the stent is in the first delivery diameter configuration.

8. The stent of claim **6**, wherein the substantially straight portion of the at least one undulating link is perpendicular to the stent longitudinal axis when the stent is in the second expanded diameter configuration.

9. The stent of claim **2**, wherein at least one of the undulating links comprise a plurality of bends.

10. The stent of claim **2**, wherein each cylindrical ring comprises a plurality of peaks and valleys.

11. The stent of claim **10**, wherein two peaks are positioned between each valley.

12. The stent of claim **10**, wherein the peaks of each cylindrical ring are in phase with the peaks of an adjacent cylindrical ring.

13. The stent of claim **2**, wherein the undulating links are configured to provide flexibility to the stent.

14. The stent of claim **2**, wherein the cylindrical rings are configured to provide flexibility to the stent.

15. The stent of claim 2, wherein the stent is formed from a tube.

16. The stent of claim 2, wherein the stent is formed from a metal alloy.

17. The stent of claim 2, wherein the stent is formed from stainless steel.

18. The stent of claim 2, wherein the stent is formed from a shape memory alloy.

19. The stent of claim 18, wherein the stent is formed from the group of shape memory alloys consisting of nickel titanium and nickel/titanium/vanadium.

20. The stent of claim 2, wherein the stent is formed from a pseudoelastic metal alloy.

21. The stent of claim 20, wherein the stent is formed from the group of pseudoelastic metal alloys consisting of nickel titanium and nickel/titanium/vanadium.

22. The stent of claim 2, wherein at least a portion of the central section is provided with a cover.

23. The stent of claim 22, wherein the stent cover is formed of a polymer.

24. The stent of claim 23, wherein the polymer cover is taken from the group of polymers including PTFE and ePTFE.

25. The stent of claim 24, wherein the stent cover is attached to the struts of the central section by an adhesive.

26. The stent of claim 25, wherein the stent cover is attached to the struts of the central section by laser bonding.

27. The stent of claim 2, wherein at least a portion of the distal section rings are coated with a therapeutic drug to reduce cell growth distal to the vulnerable plaque.

28. The stent of claim 2, wherein at least a portion of the proximal section rings are coated with a therapeutic drug to reduce cell growth proximal to the vulnerable plaque.

29. The stent of claim 2, wherein at least a portion of the distal section rings and the proximal section rings are coated with a therapeutic drug to reduce cell growth on either side of the vulnerable plaque.

30. A stent for implanting in a body lumen, comprising:

a distal section, a proximal section, and a central section positioned between the distal section and the proximal section, each section being aligned along a common longitudinal axis forming the stent;

the distal section having a first strut pattern, the proximal section having a second strut pattern, and the central section having a third strut pattern;

wherein the third strut pattern has a substantially uniform repeating series of zig-zagging struts that form a single ring;

the distal section and the proximal section having cylindrical rings having a first longitudinal length, and the central section having a cylindrical ring having a second longitudinal length, the first longitudinal length being shorter than the second longitudinal length;

the first strut pattern having a first metallic surface area;

the second strut pattern having a second metallic surface area;

the third strut pattern having a third metallic surface area;

the third strut pattern having a substantially uniform air to metal ratio; and

at least one of the first and second metallic surface areas being greater that the metallic surface area of the third strut pattern.

31. The stent of claim 30, wherein the metallic surface areas of at least one of the first and second strut pattern being less than about 20%.

32. The stent of claim 30, wherein the first, second and third strut patterns are in an expanded configuration.

33. A stent for treating vulnerable plaque, comprising:

a distal section, a proximal section, and a central section positioned between the distal section and the proximal section, each section being aligned along a common longitudinal axis forming the stent;

the distal section and the proximal section having a first strut pattern and a second strut pattern respectively, and the central section having a third strut pattern;

wherein the central section has a uniform repeating series of zig-zagging struts that form a single ring;

the distal section and the proximal section having cylindrical rings having a first longitudinal length, and the central section having a cylindrical ring having a second longitudinal length, the first longitudinal length being shorter than the second longitudinal length;

the central section having a substantially uniform air to metal ratio;

each strut pattern having curved portions and straight portions configured to allow the patterns to compress and expand; and

the third strut pattern having fewer curved portions and straight portions that the first and second strut patterns.

34. The stent of claim 33, wherein the third strut pattern is disposed between the first and the second strut patterns.

35. The stent of claim 33, wherein the first strut pattern is different than the second strut pattern.

36. The stent of claim 33, wherein the first strut pattern and the second strut pattern are substantially the same.

37. The stent of claim 33, wherein the third strut pattern is different than the first and second strut patterns.

38. The stent of claim 33, wherein the third strut pattern has an air to metal ratio that is higher than an air to metal ratio of the first or second strut pattern.

39. An intravascular stent for use in a body lumen, comprising:

a distal section, a proximal section, and a central section positioned between the distal section and the proximal section, each section being aligned along a common longitudinal axis forming the stent;

the distal section and the proximal section having cylindrical rings having a first longitudinal length, and the central section having a cylindrical ring having a second longitudinal length, the first longitudinal length being shorter than the second longitudinal length;

the distal section and the proximal section having a first strut pattern and a second strut pattern respectively, and the central section having a third strut pattern;

the third strut pattern having a substantially uniform repeating series of struts that form a single central ring wherein each strut is directly attached to an adjacent strut to define a zig-zag pattern;

the first strut pattern and the second strut pattern being more dense than the third strut pattern;

the third strut pattern having a substantially uniform air to metal ratio; and

wherein the third strut pattern includes straight struts, at least some of the straight struts having undulating members.

40. The stent of claim 39, wherein the stent is formed from a metal alloy.

41. The stent of claim 39, wherein the stent is formed from stainless steel.

42. The stent of claim 39, wherein at least a portion of the central section is provided with a polymer cover.

43. The stent of claim 39, wherein at least a portion of the distal section rings are coated with a therapeutic drug.

44. The stent of claim 39, wherein at least a portion of the proximal section rings are coated with a therapeutic drug.

45. The stent of claim 39, wherein at least a portion of the distal section rings and the proximal section rings are coated with a therapeutic drug.

46. An intravascular stent for use in a body lumen, comprising:

a distal section, a proximal section, and a central section positioned between the distal section and the proximal section, each section being aligned along a common longitudinal axis forming the stent;

the distal section and the proximal section having cylindrical rings having a first longitudinal length, and the central section having a cylindrical ring having a second longitudinal length, the first longitudinal length being shorter than the second longitudinal length;

the distal section and the proximal section having a first strut pattern and a second strut pattern respectively, and the central section having a third strut pattern;

the third strut pattern having a substantially uniform repeating series of struts that form a single central ring wherein each strut is directly attached to an adjacent strut to define a zig-zag pattern;

the first strut pattern and the second strut pattern being more dense than the third strut pattern;

the third strut pattern having a substantially uniform air to metal ratio; and

wherein the third strut pattern includes undulating struts.

47. The stent of claim 46, wherein the stent is formed from a metal alloy.

48. The stent of claim 46, wherein the stent is formed from stainless steel.

49. The stent of claim 46, wherein at least a portion of the central section is provided with a polymer cover.

50. The stent of claim 46, wherein at least a portion of the distal section rings are coated with a therapeutic drug.

51. The stent of claim 46, wherein at least a portion of the proximal section rings are coated with a therapeutic drug.

52. The stent of claim 46, wherein at least a portion of the distal section rings and the proximal section rings are coated with a therapeutic drug.

53. An intravascular stent for use in a body lumen, comprising:

a distal section, a proximal section, and a central section positioned between the distal section and the proximal section, each section being aligned along a common longitudinal axis forming the stent;

the distal section and the proximal section having cylindrical rings having a first longitudinal length, and the central section having a cylindrical ring having a second longitudinal length, the first longitudinal length being shorter than the second longitudinal length;

the distal section and the proximal section having a first strut pattern and a second strut pattern respectively, and the central section having a third strut pattern;

the third strut pattern having a substantially uniform repeating series of struts that form a single central ring wherein each strut is directly attached to an adjacent strut to define a zig-zag pattern;

the first strut pattern and the second strut pattern being more dense than the third strut pattern; and

the third strut pattern having a substantially uniform air to metal ratio; and

wherein the distal section and the proximal section each have a plurality of cylindrical rings interconnected along the longitudinal axis by links.

54. The stent of claim 53, wherein the stent is formed from a metal alloy.

55. The stent of claim 53, wherein the stent is formed from stainless steel.

56. The stent of claim 53, wherein at least a portion of the central section is provided with a polymer cover.

57. The stent of claim 53, wherein at least a portion of the distal section rings are coated with a therapeutic drug.

58. The stent of claim 53, wherein at least a portion of the proximal section rings are coated with a therapeutic drug.

59. The stent of claim 53, wherein at least a portion of the distal section rings and the proximal section rings are coated with a therapeutic drug.

60. The stent of claim 53, wherein the links have a substantially straight configuration.

61. The stent of claim 53, wherein the links have an undulating configuration.

62. The stent of claim 53, wherein the links have a straight section and an undulating section.

63. The stent of claim 53, wherein the links have a straight section and a curved section.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,163,553 B2
APPLICATION NO. : 10/034208
DATED : January 16, 2007
INVENTOR(S) : Timothy A. Limon

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page, Item 57, ABSTRACT, delete "for a an intravascular stent" and insert --for an intravascular stent--.

Column 2,
Line 51, delete "a undulating or serpentine" and insert --an undulating or a serpentine--.

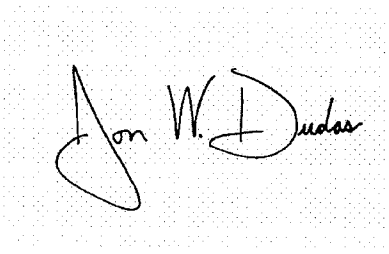
Column 9,
Line 9, delete "iradium" and insert --iridium--.

Column 13,
Line 61, delete "that" and insert --than--.

Column 14,
Line 22, delete "that" and insert --than--.

Signed and Sealed this

Seventeenth Day of April, 2007



JON W. DUDAS
Director of the United States Patent and Trademark Office

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(12) **United States Patent**
Pacetti

(10) **Patent No.: US 7,175,874 B1**
(45) **Date of Patent: Feb. 13, 2007**

(54) **APPARATUS AND METHOD FOR COATING IMPLANTABLE DEVICES**

(75) Inventor: **Stephen D. Pacetti**, San Jose, CA (US)

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 706 days.

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(51) **Int. Cl.**
B05D 1/04 (2006.01)

(52) **U.S. Cl.** **427/2.25**; 427/426

(58) **Field of Classification Search** 623/1.42–1.46; 427/2.24–2.25, 2.3, 2.21, 446, 528, 426
See application file for complete search history.

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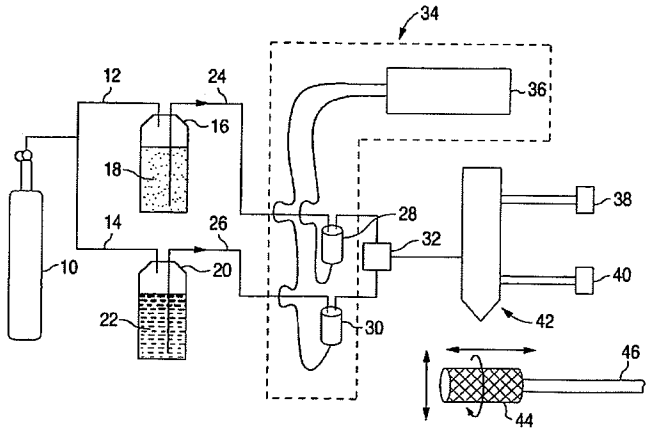
(74) *Attorney, Agent, or Firm*—Squire, Sanders & Dempsey L.L.P.

(57) **ABSTRACT**

A coating for implantable devices, such as stents, and a method of making the same is disclosed. Moreover, an apparatus for depositing the coating is disclosed.

50 Claims, 5 Drawing Sheets



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